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(54) **MULTIPLE COIL SYSTEM FOR TRACKING A MEDICAL DEVICE**

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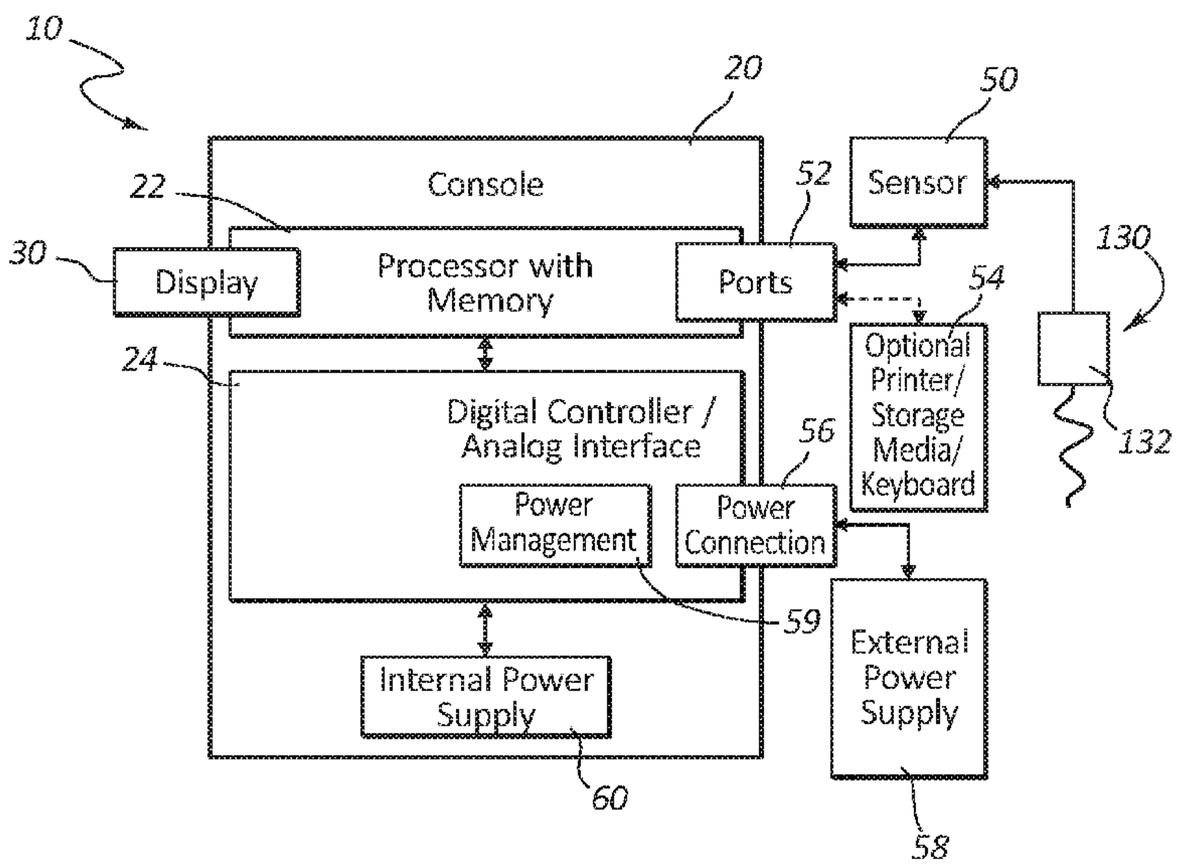
(57) **ABSTRACT**

A system for tracking the position of one or more medical devices for insertion into the body of a patient is disclosed. The system may also be used to locate one or medical devices at a later time after placement thereof. The present system employs multiple radiating elements that can be simultaneously detected by a sensor unit of the system, wherein at least one of the radiating elements is included with the medical device. Another of the radiating elements may be placed at a predetermined point on the skin of the patient to serve as a landmark to help determine the location of the medical device with respect to the landmark. Detection of the radiating elements by the sensor unit enables the relative positions of the radiating elements to be ascertained and depicted on a display, to assist a clinician in accurately positioning the medical device, such as a catheter.

19 Claims, 11 Drawing Sheets



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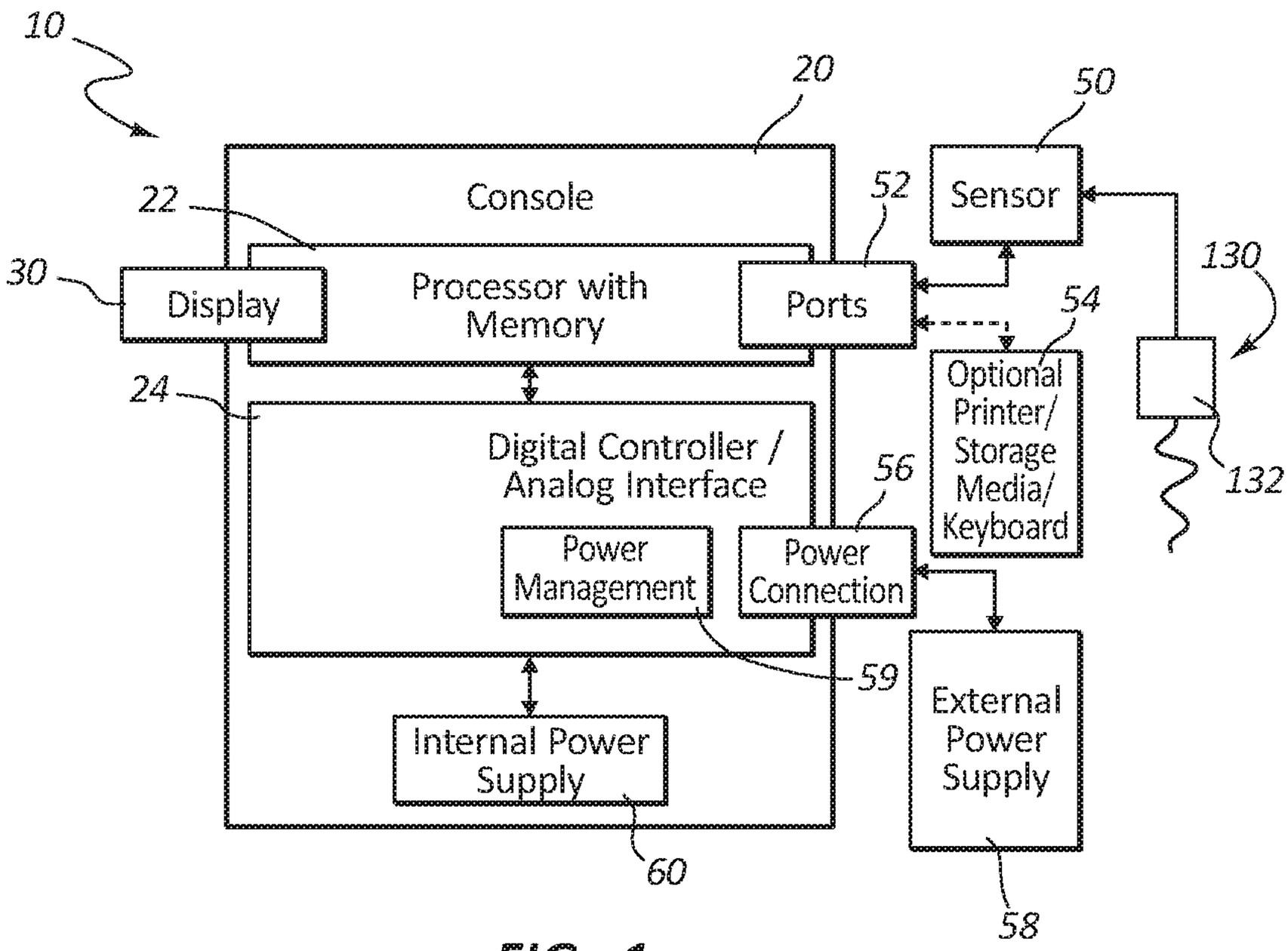
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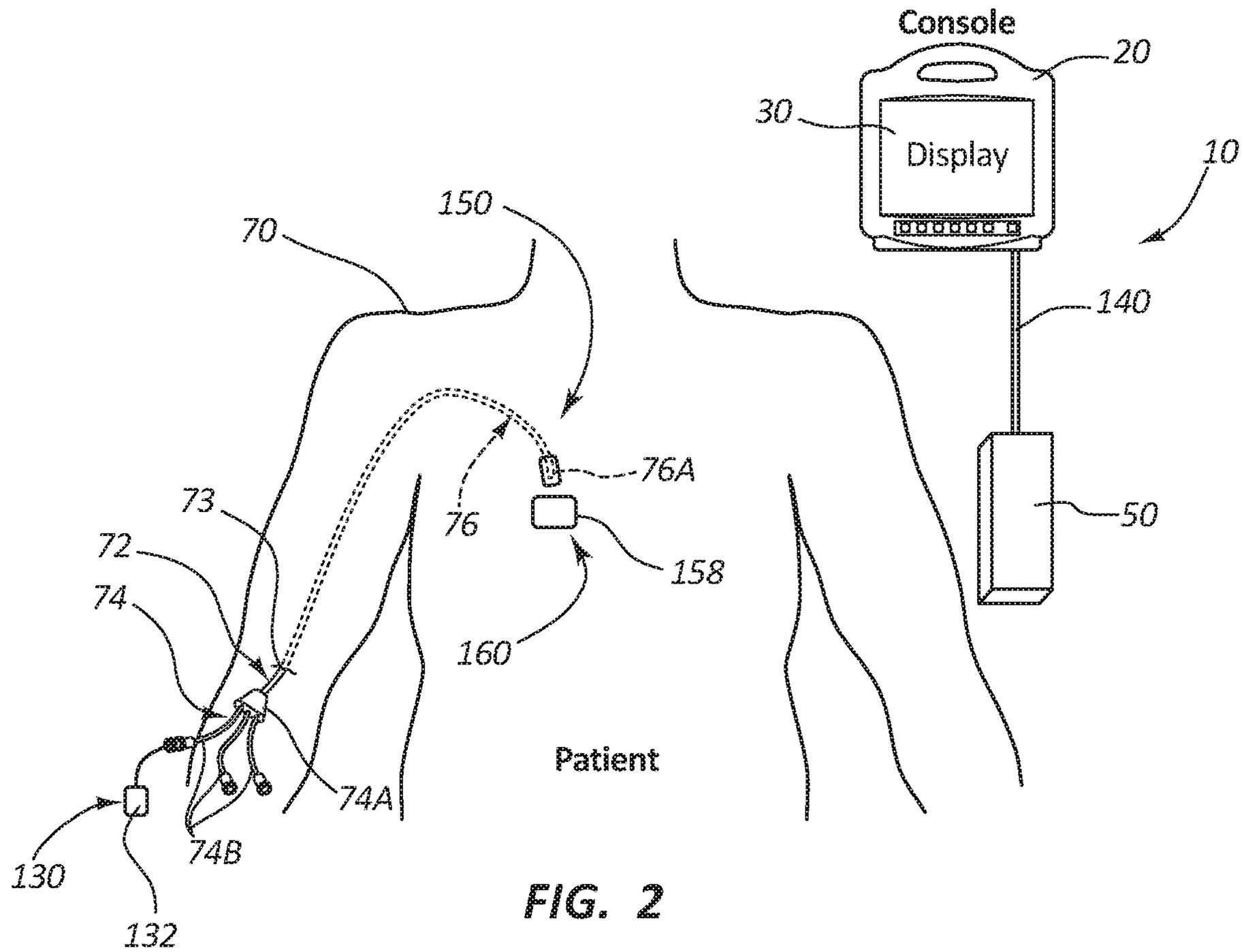
20
50
Console
22
52
Sensor
30
Display
Processor with Memory
Ports
130
54
Optional Printer/ Storage Media/ Keyboard
24
Digital Controller / Analog Interface
56
132
Power Management
Power Connection
59
External Power Supply
Internal Power Supply
60
58

FIG. 1


Console
20
30
Display
10
150
70
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76A
50
73
76
72
158
74
160
Patient
74A
74B
130
132

FIG. 2

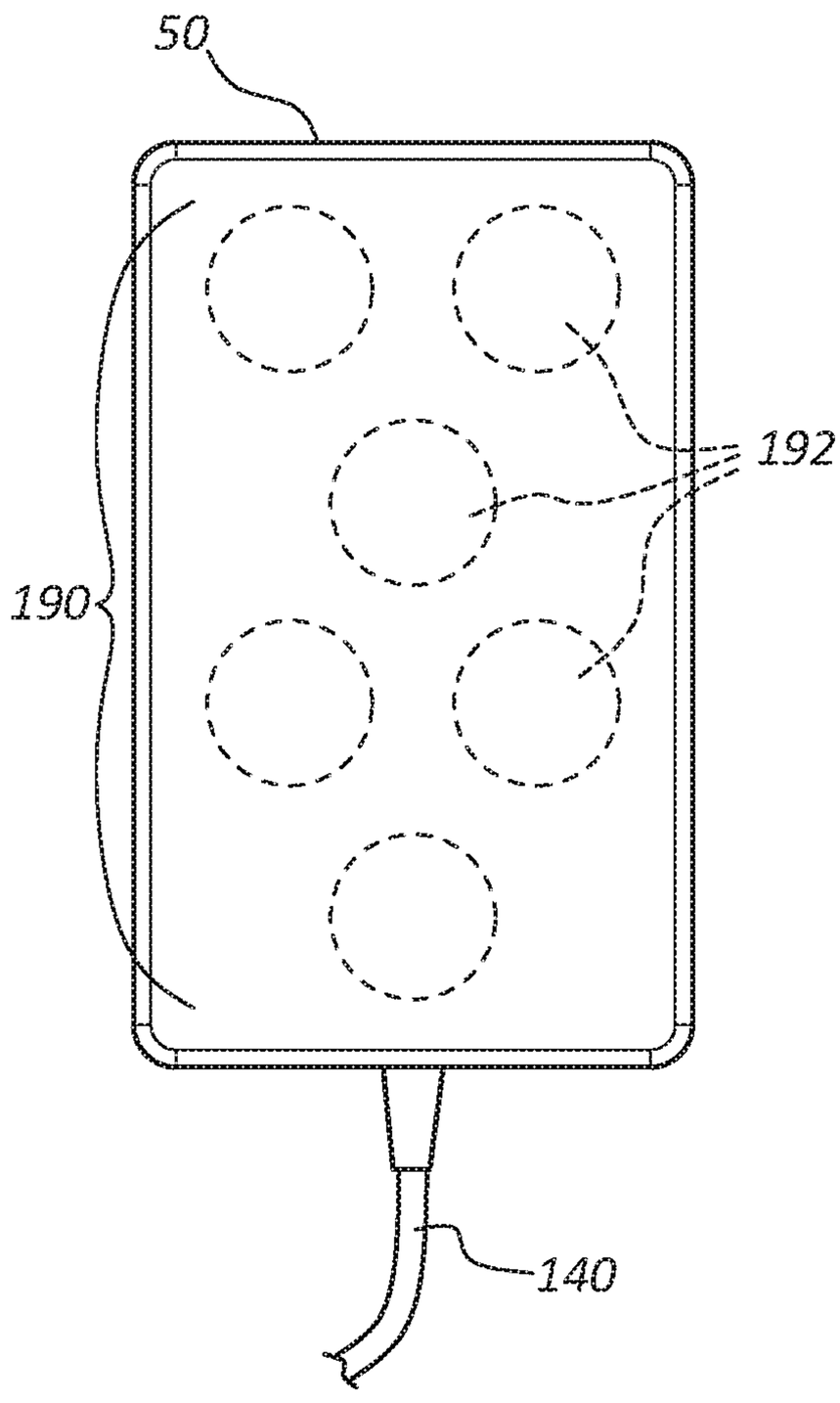


FIG. 3A

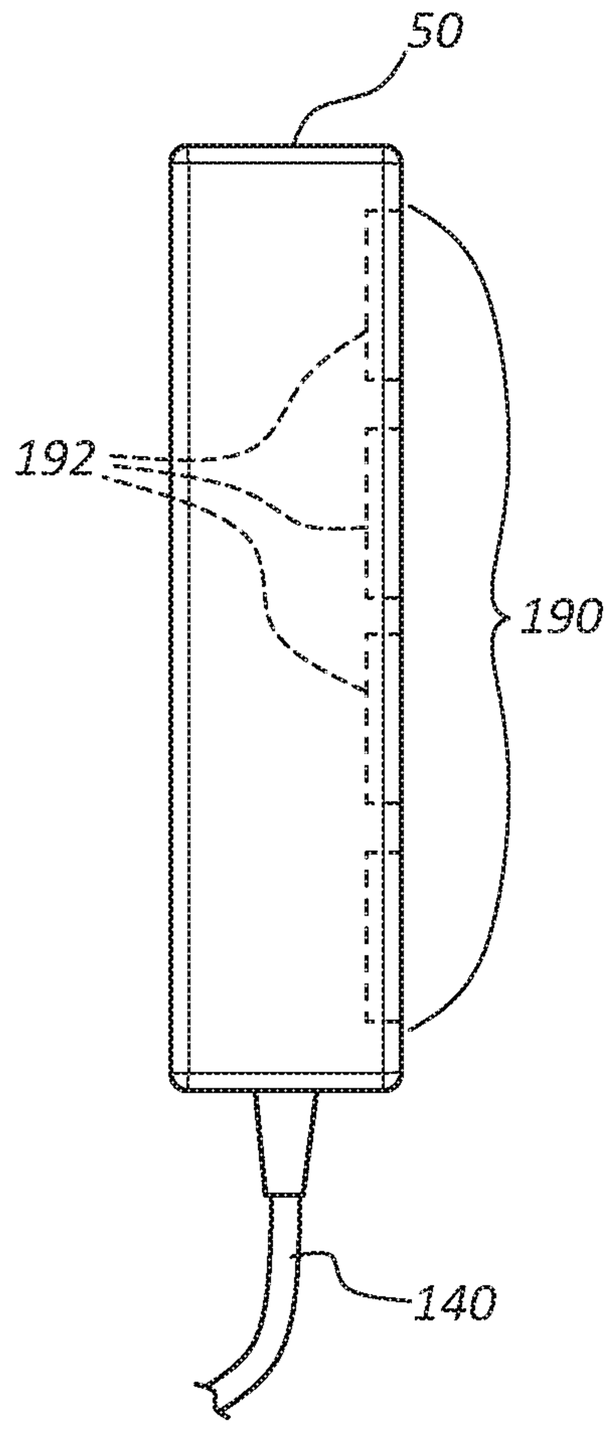


FIG. 3B

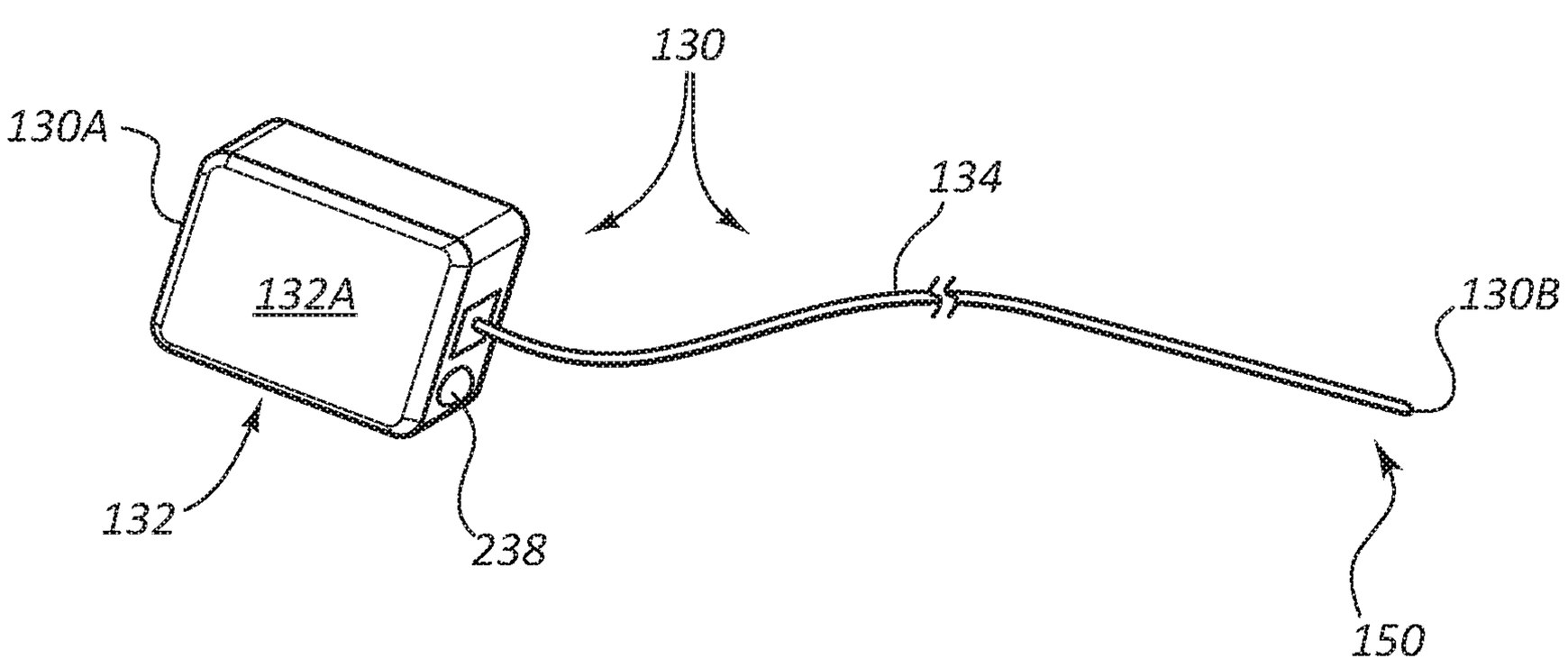
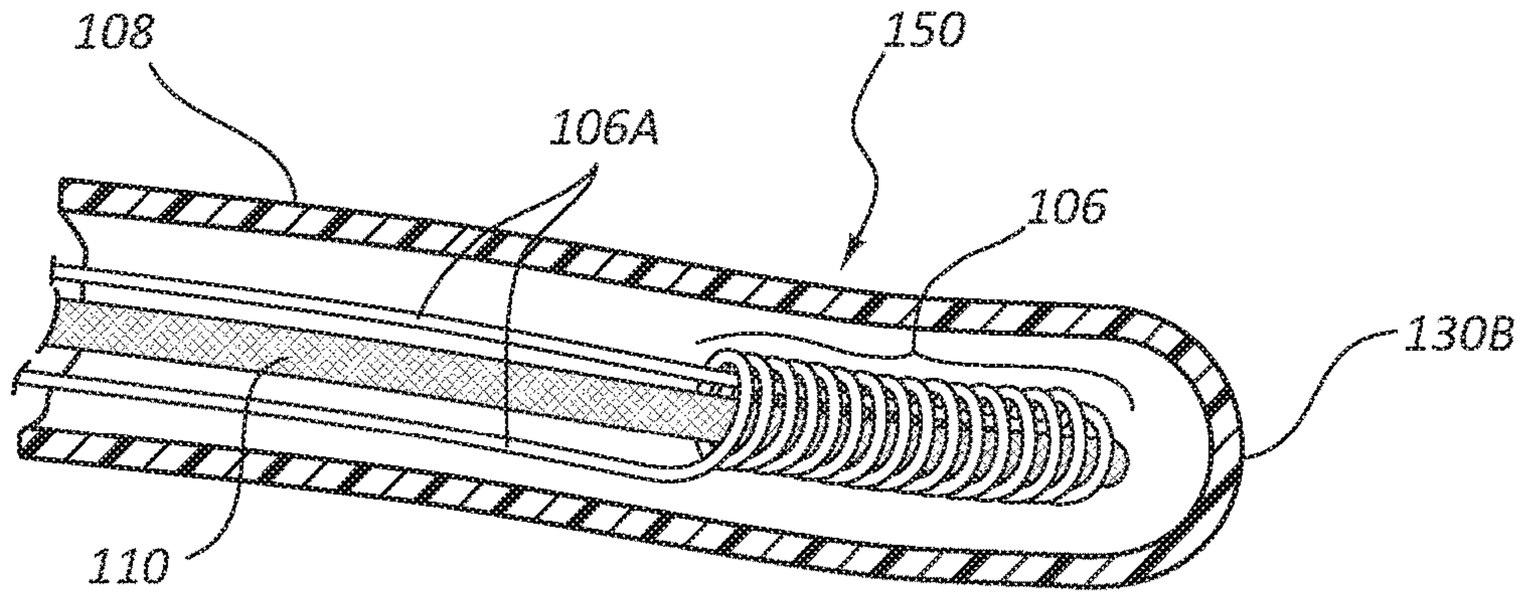


FIG. 4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150
106A
106
130B
110

FIG. 5

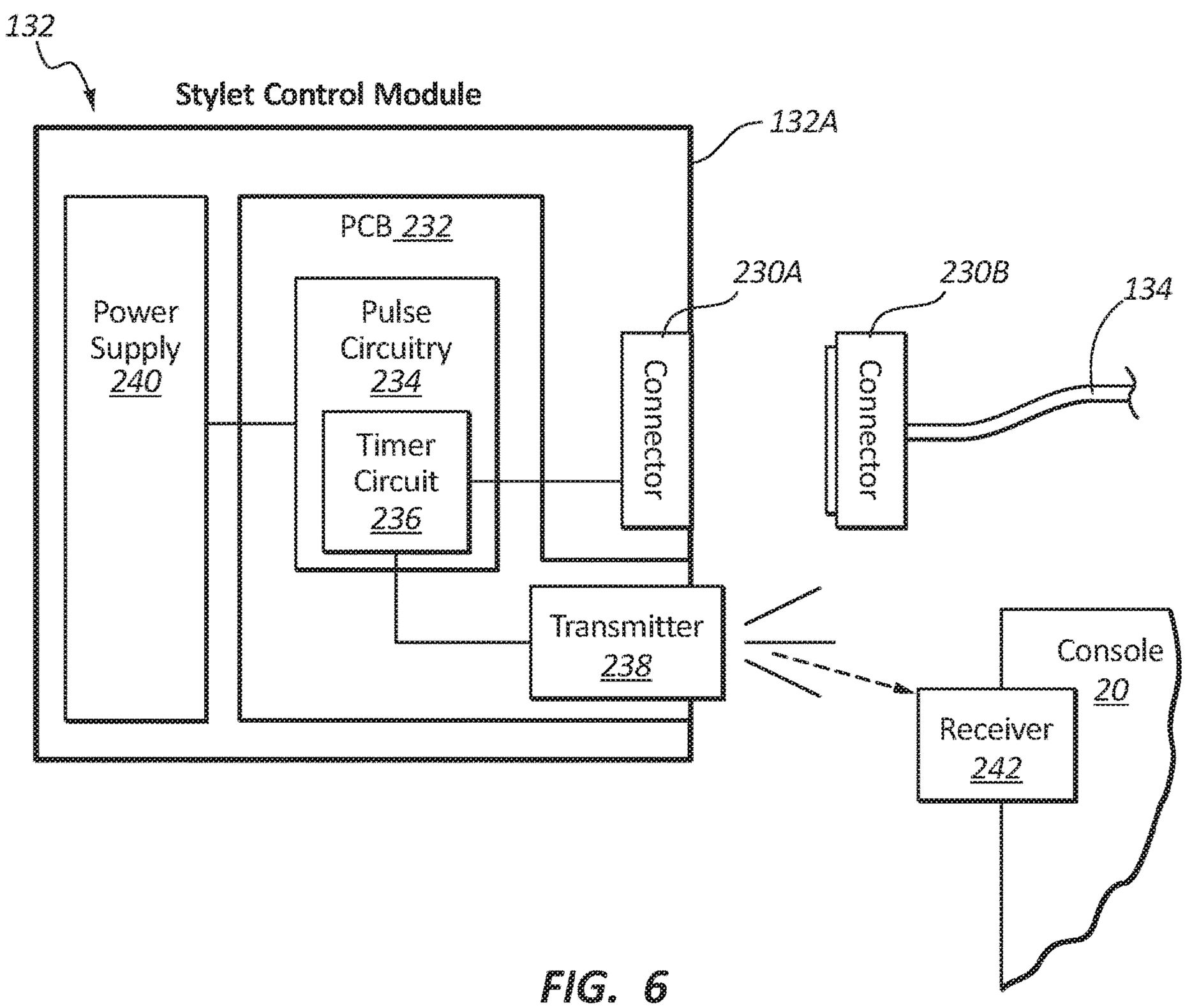

132
Stylet Control Module
132A
PCB 232
Power Supply 240
Pulse Circuitry 234
Timer Circuit 236
Transmitter 238
230A
Connector
230B
Connector
134
Console 20
Receiver 242

FIG. 6

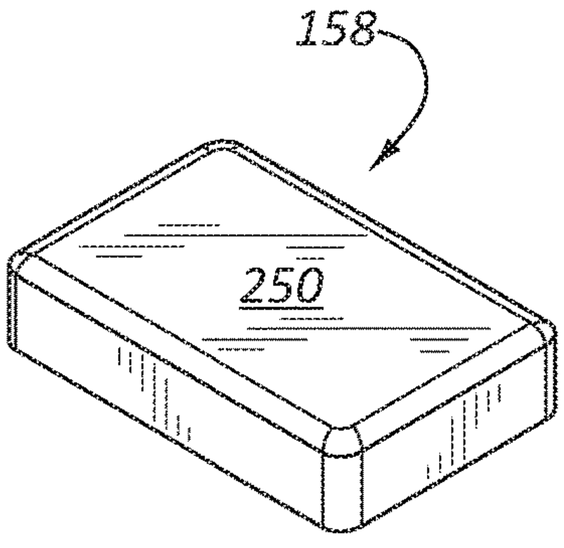


FIG. 7A

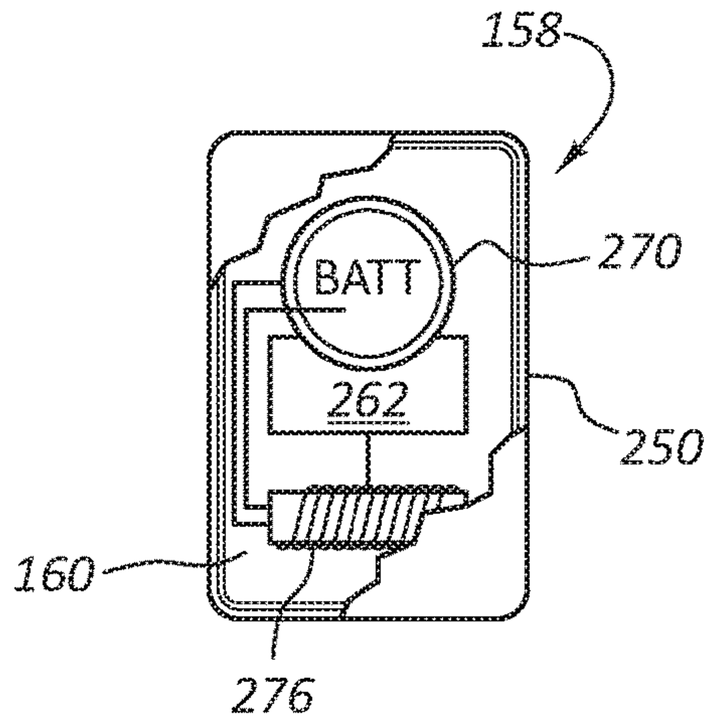


FIG. 7B

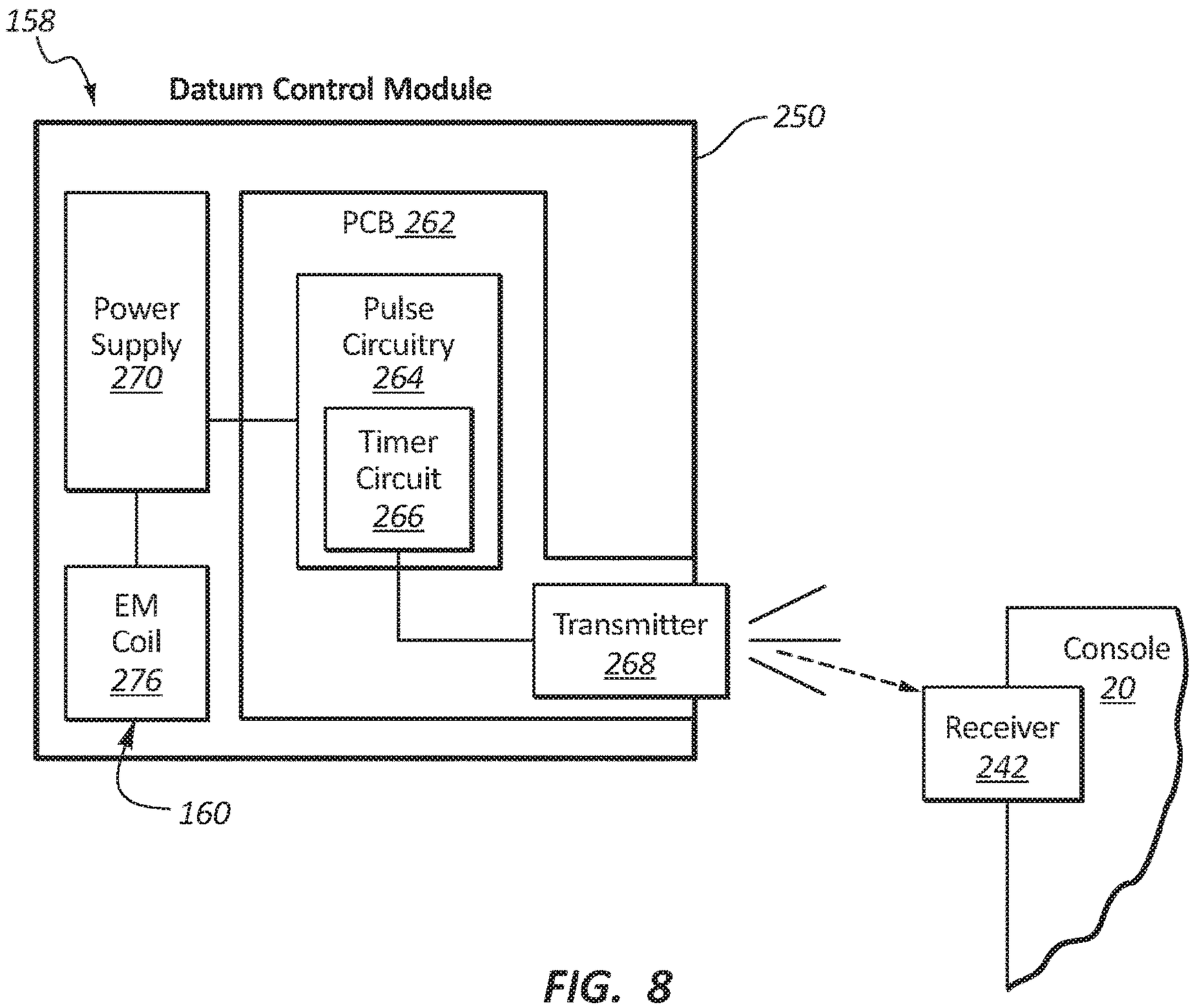
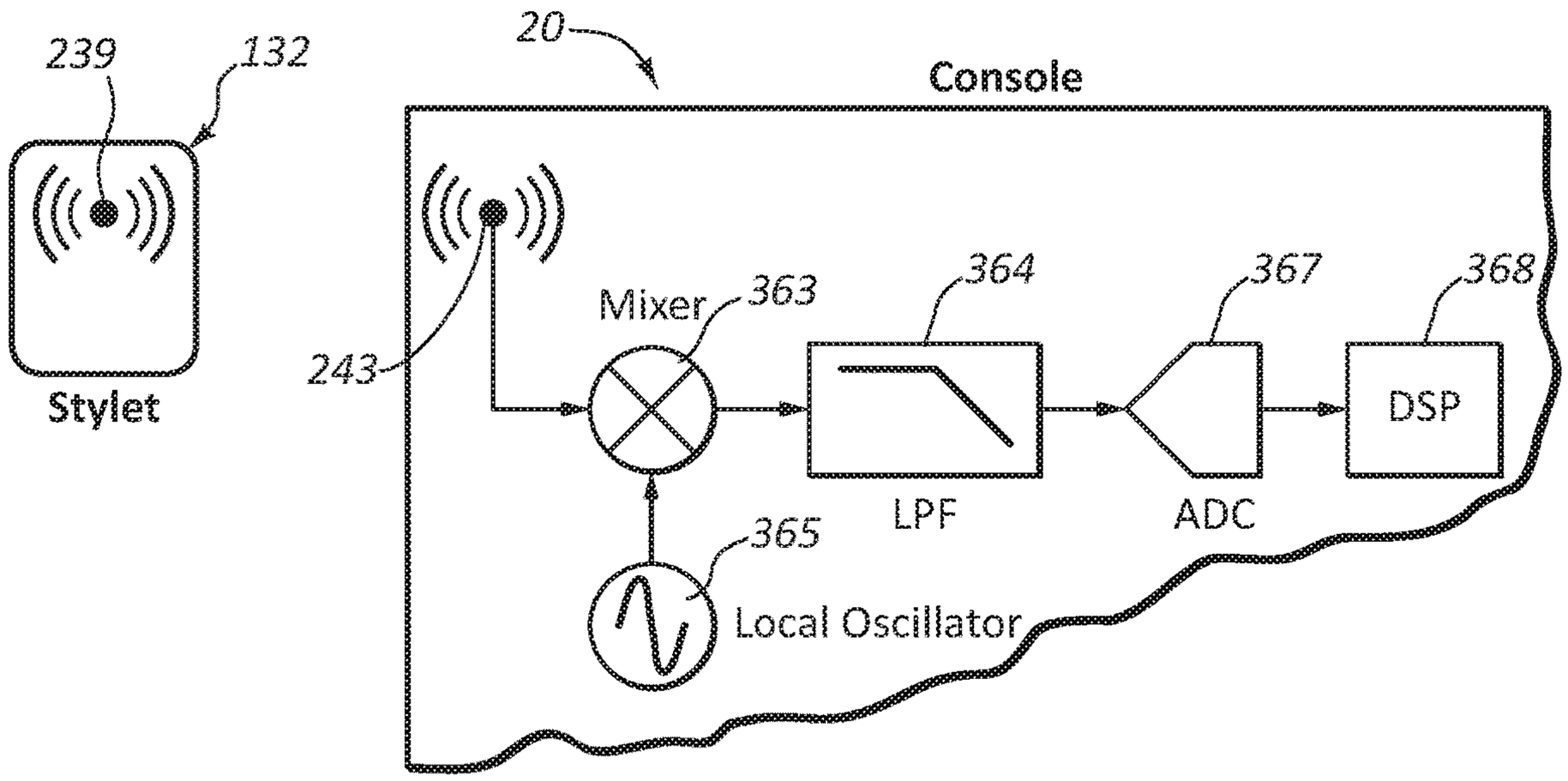


FIG. 8


239
132
Stylet
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Console
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Mixer
363
364
367
368
DSP
LPF
ADC
365
Local Oscillator

FIG. 9

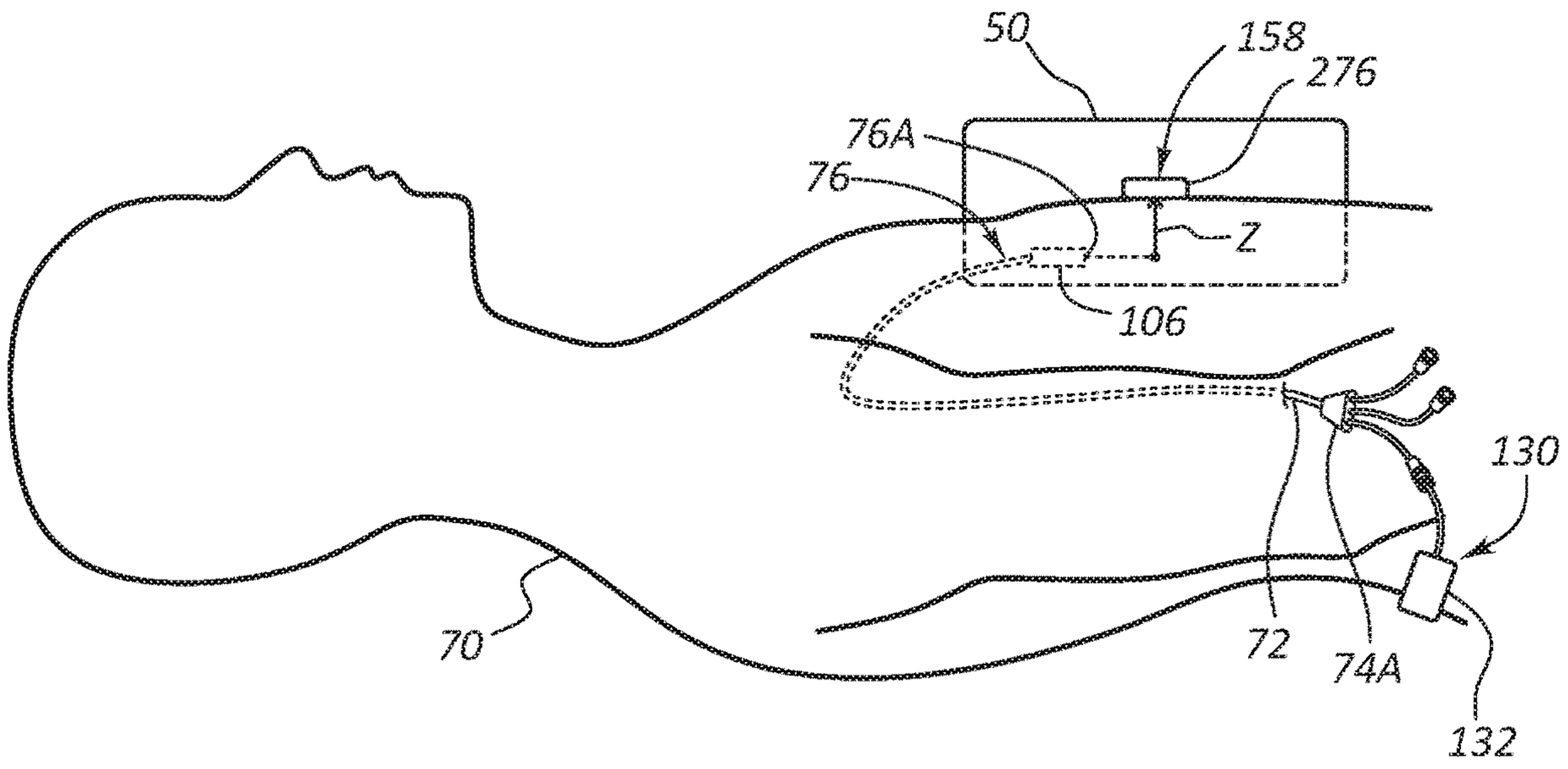
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FIG. 10

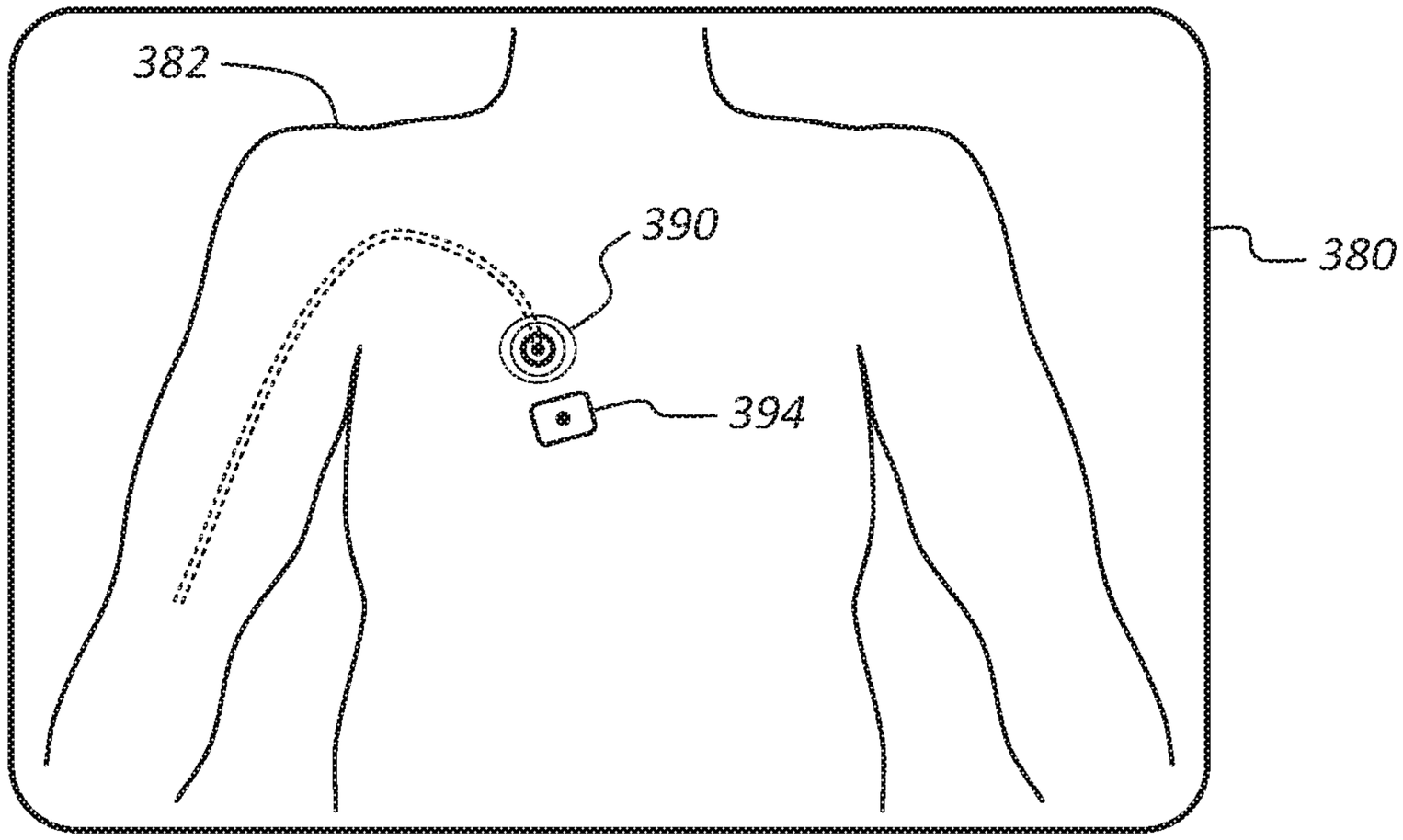


FIG. 11

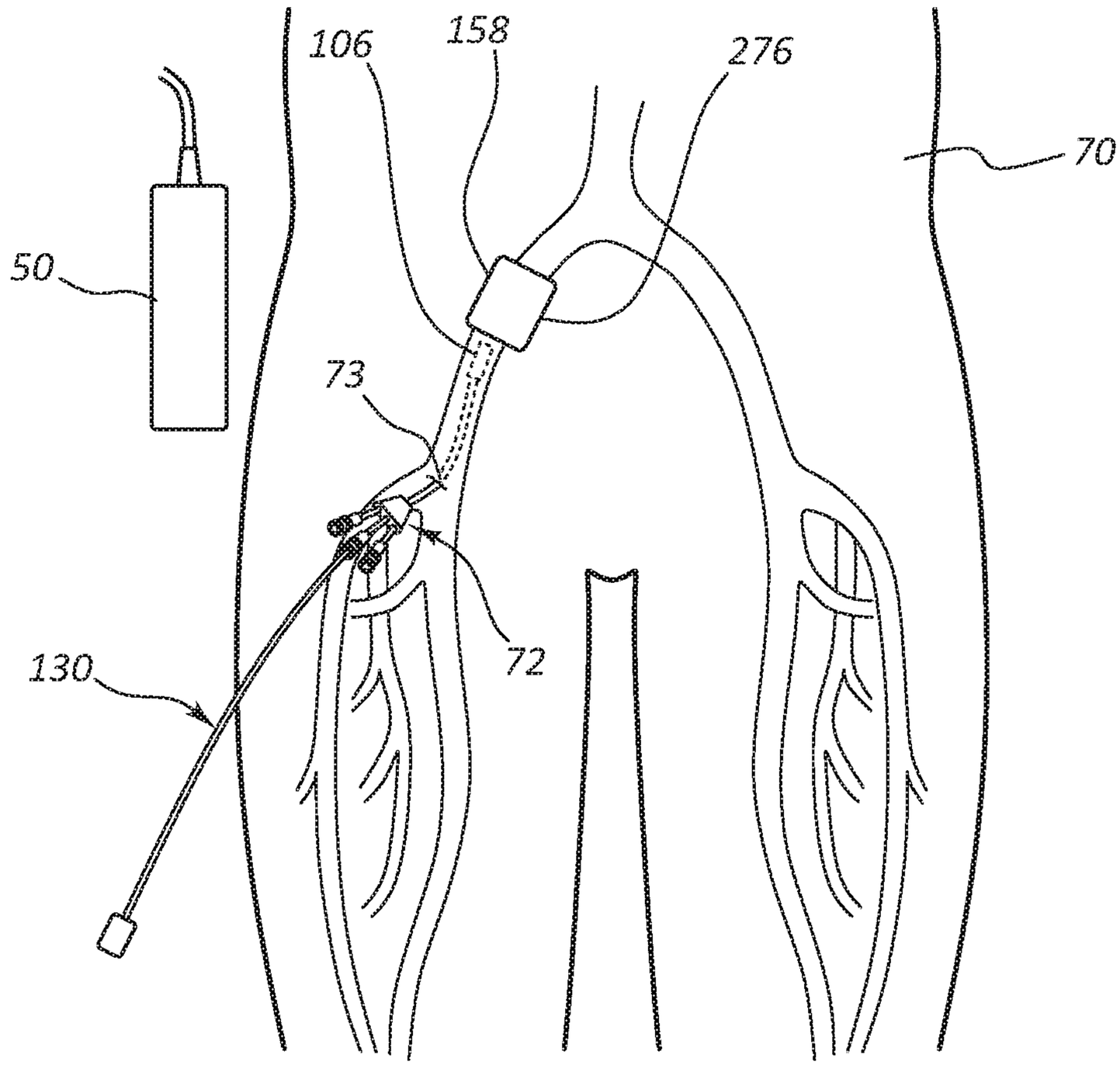


FIG. 12

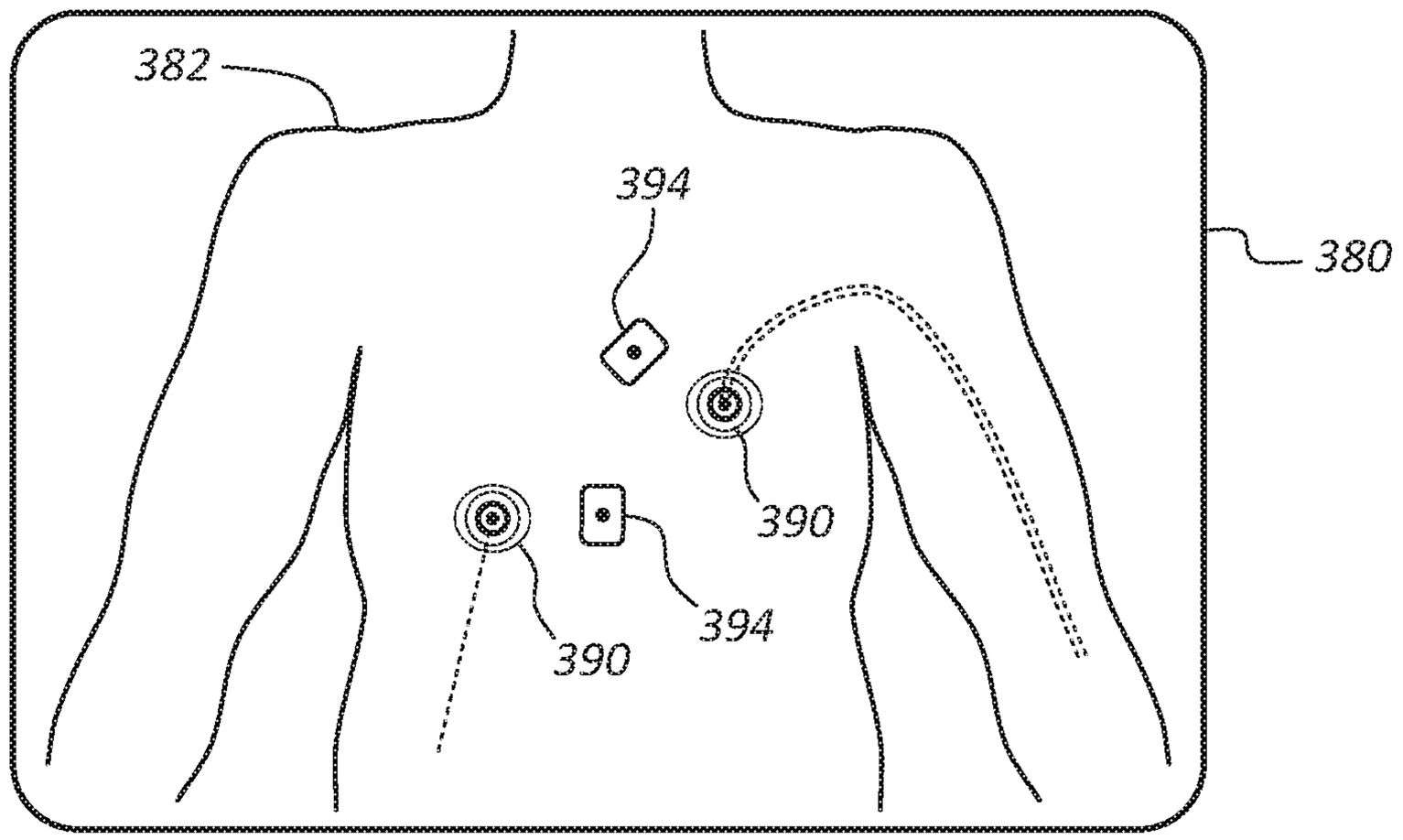


FIG. 13

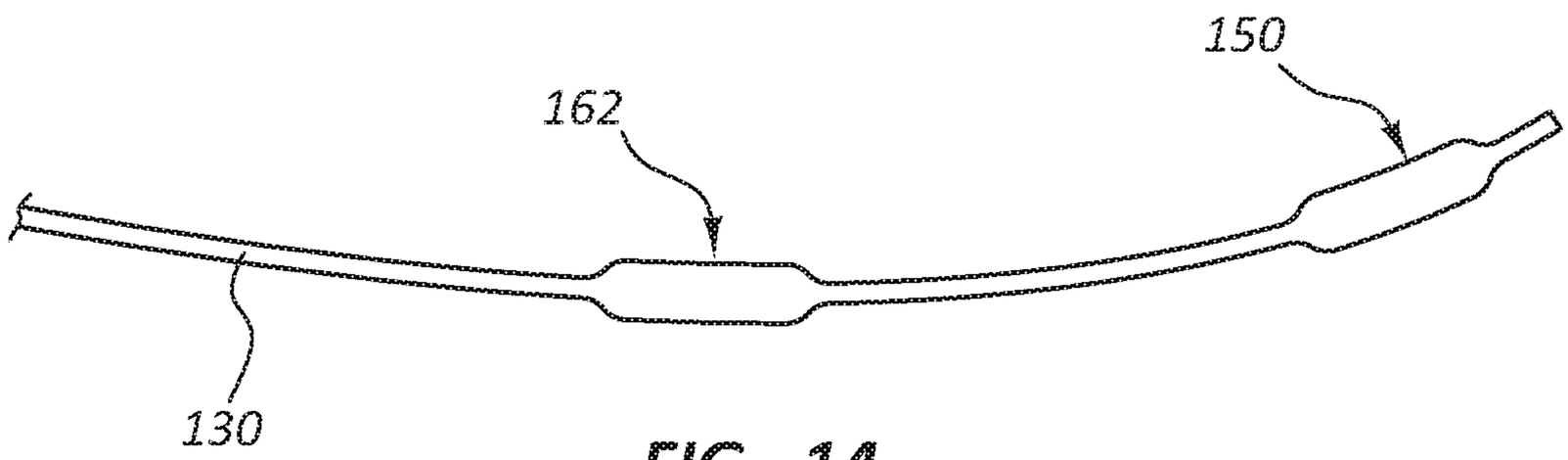


FIG. 14

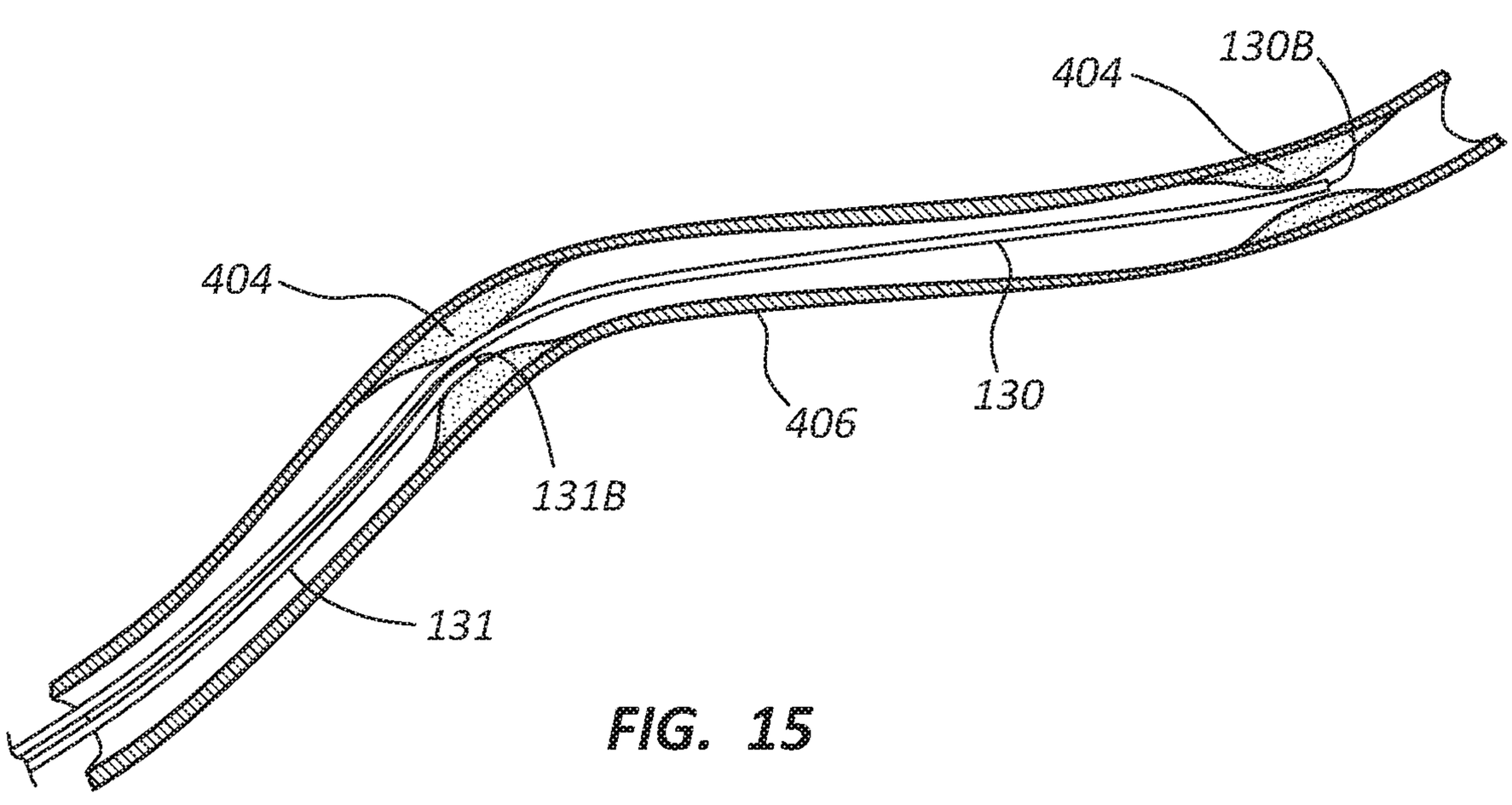
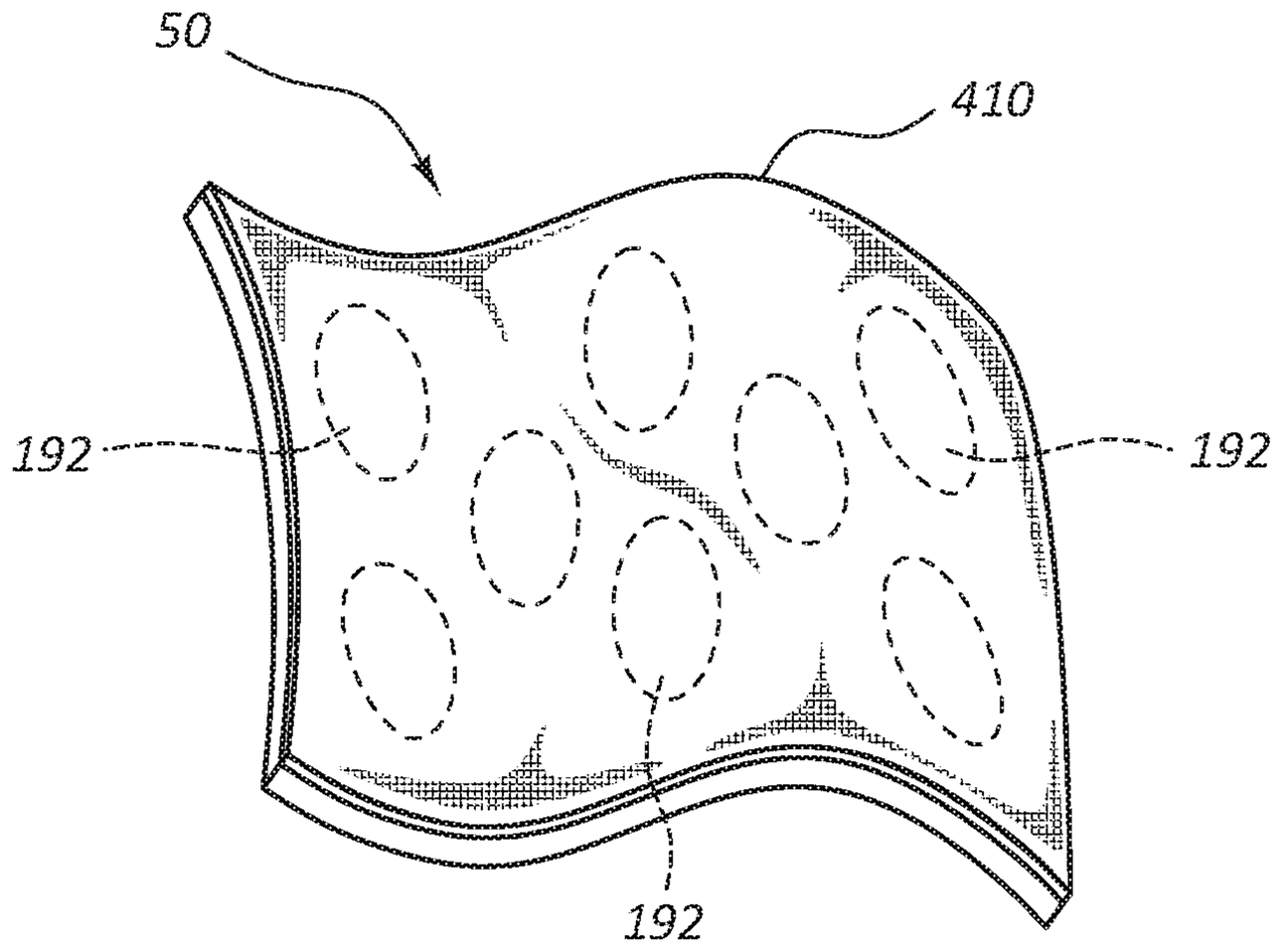


FIG. 15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192

FIG. 16

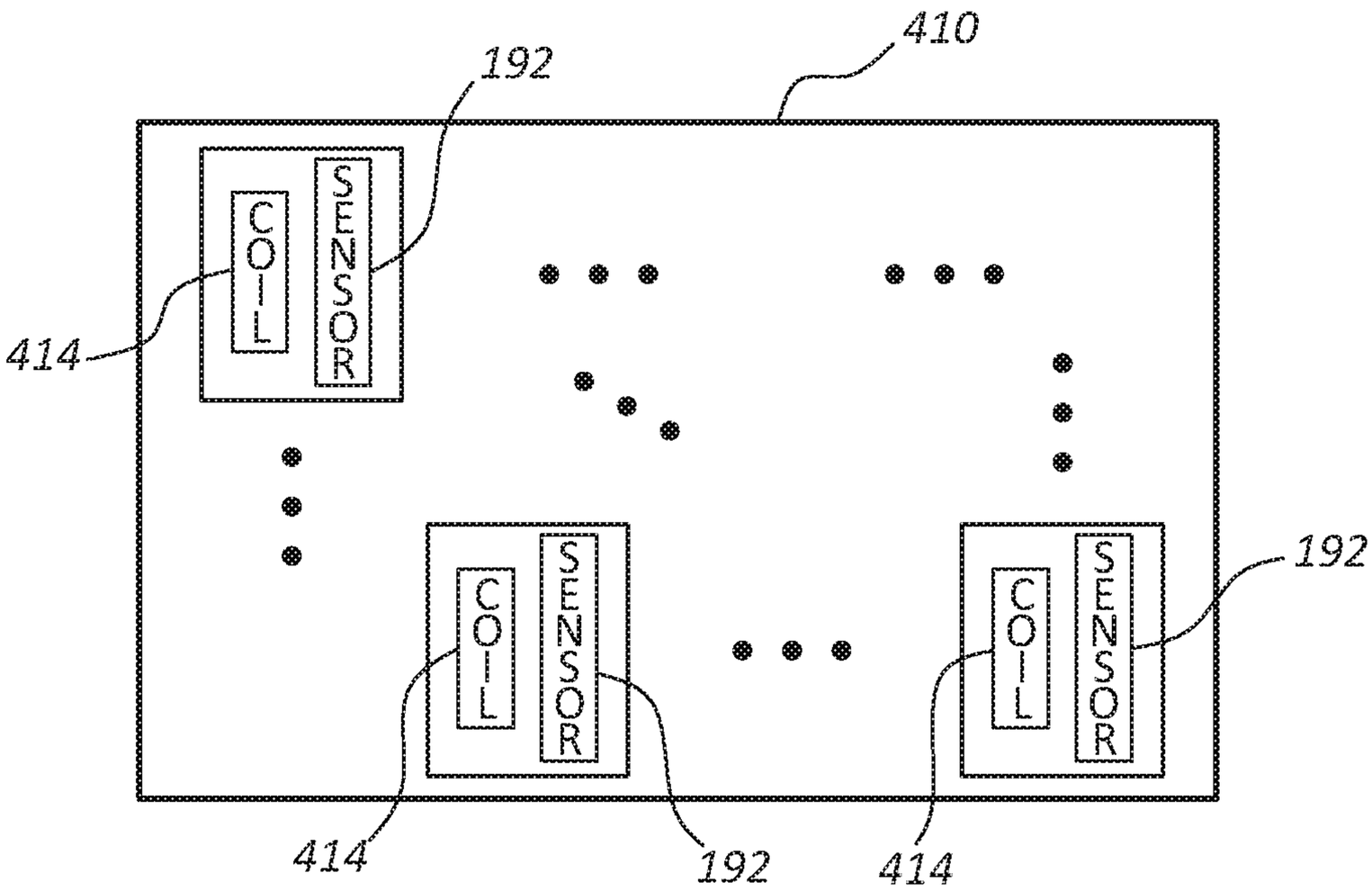
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FIG. 17

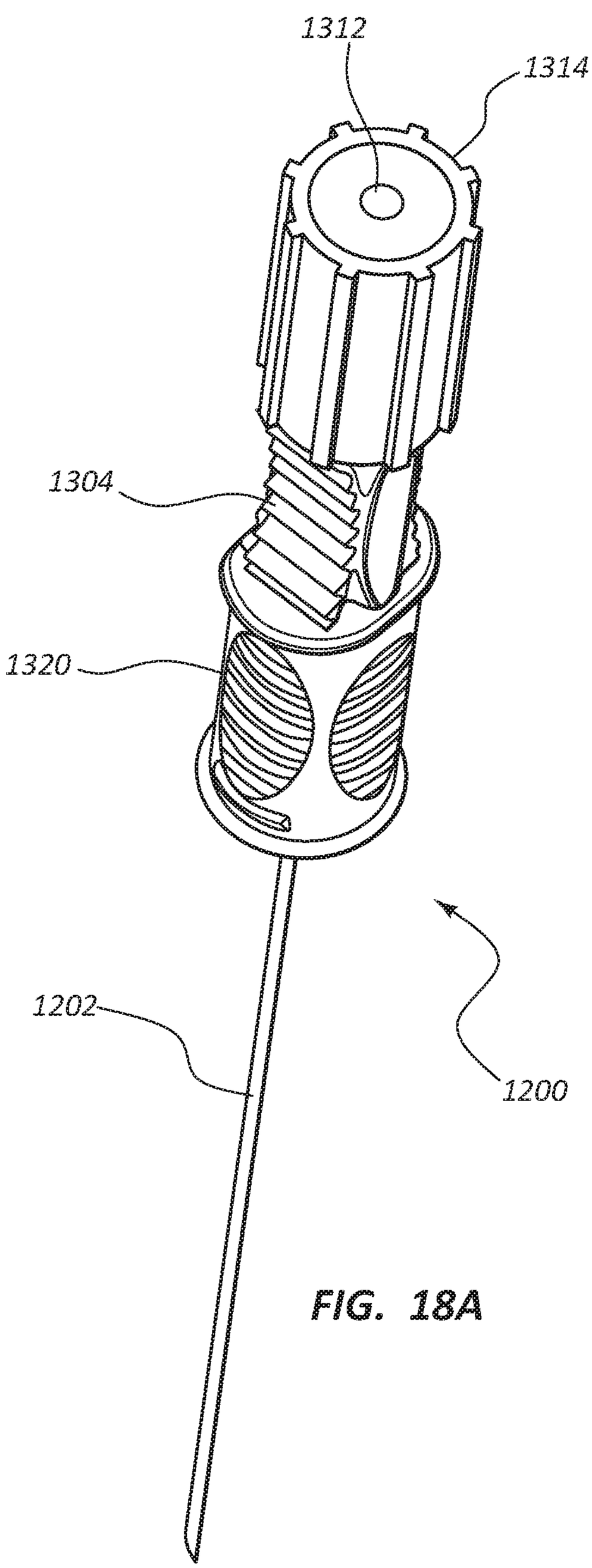


FIG. 18A

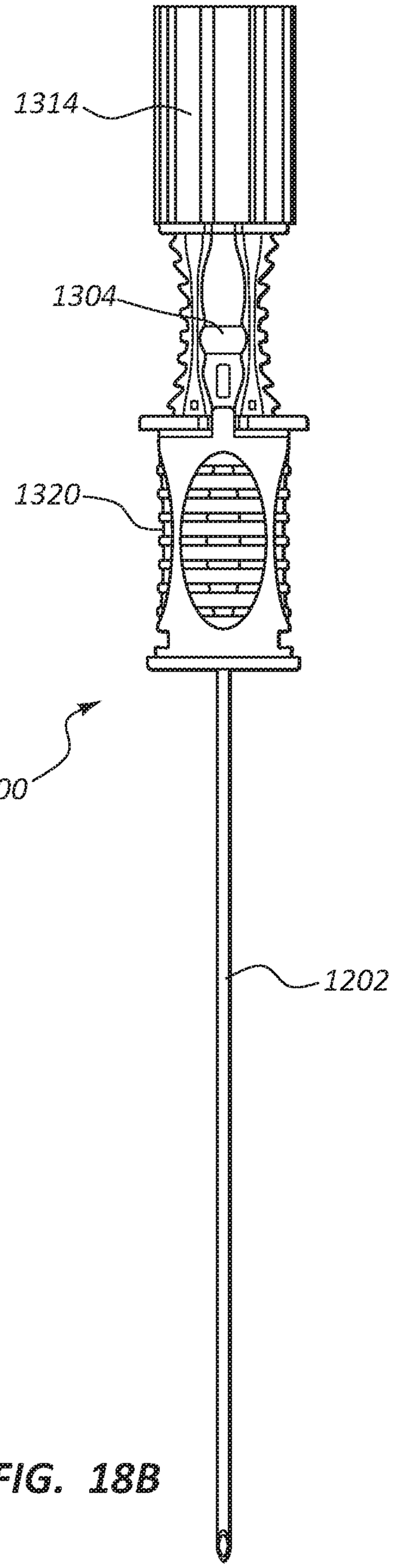
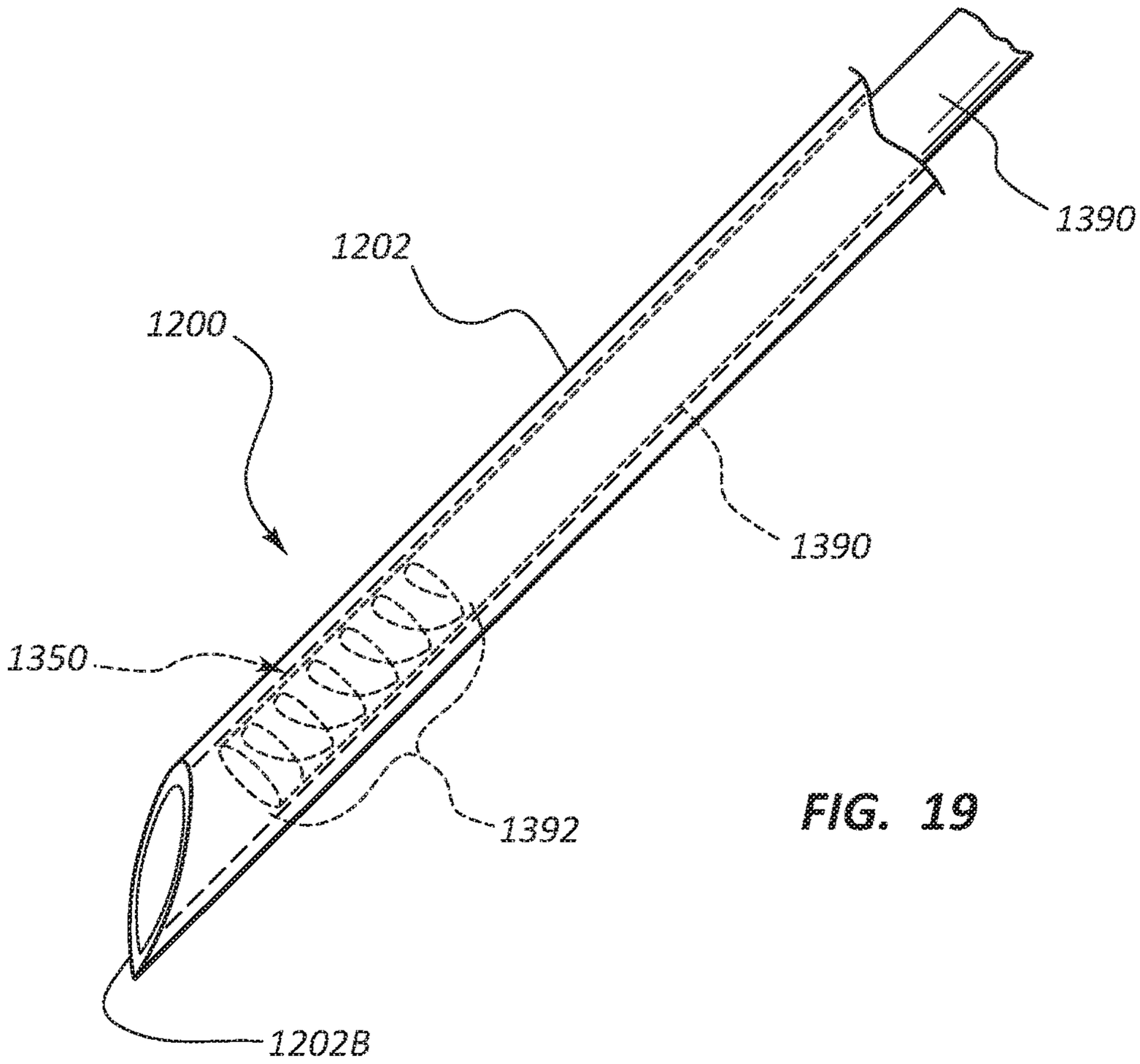


FIG. 18B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1202
1200
1390
1350
1392
1202B

FIG. 19

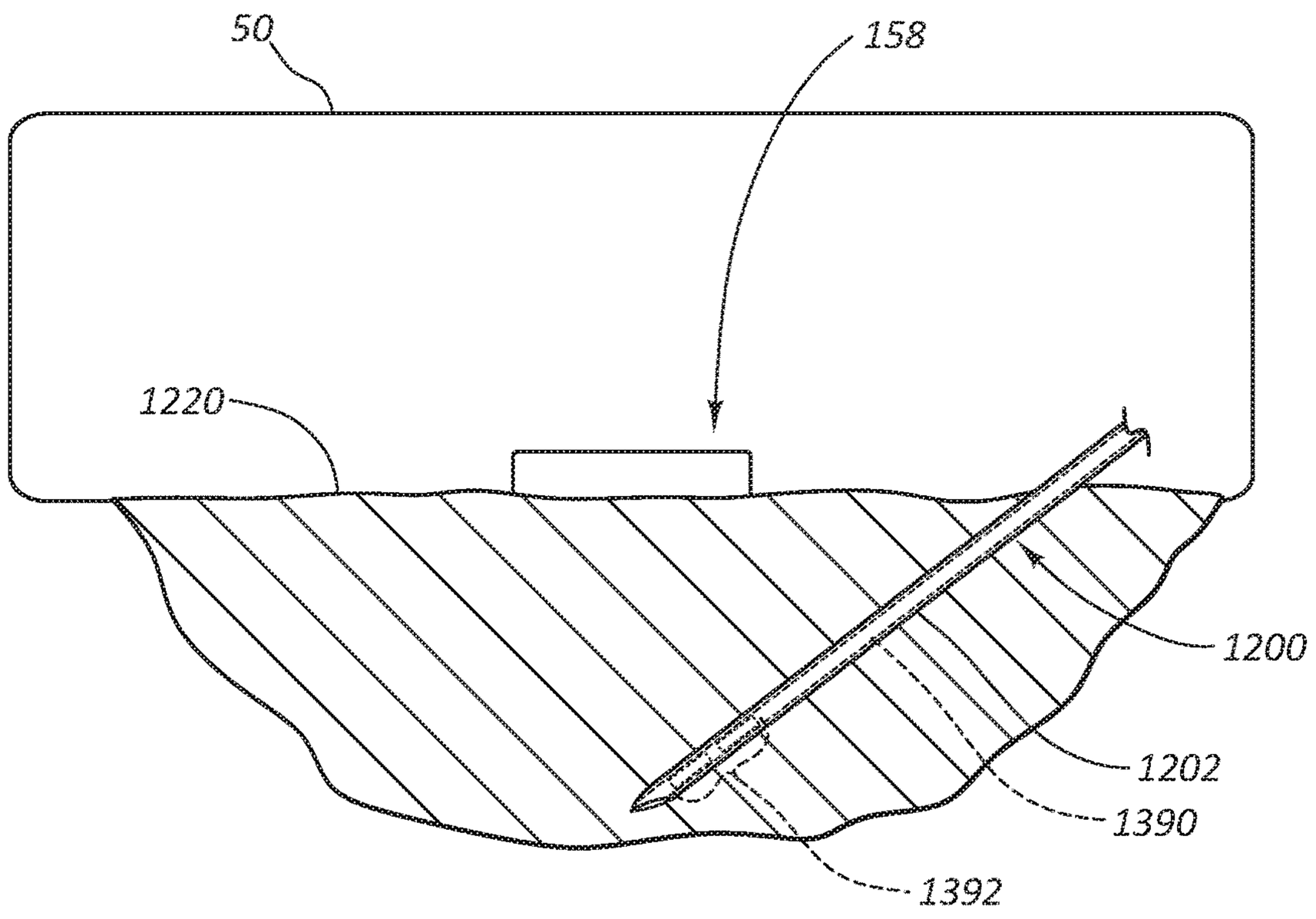
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FIG. 20

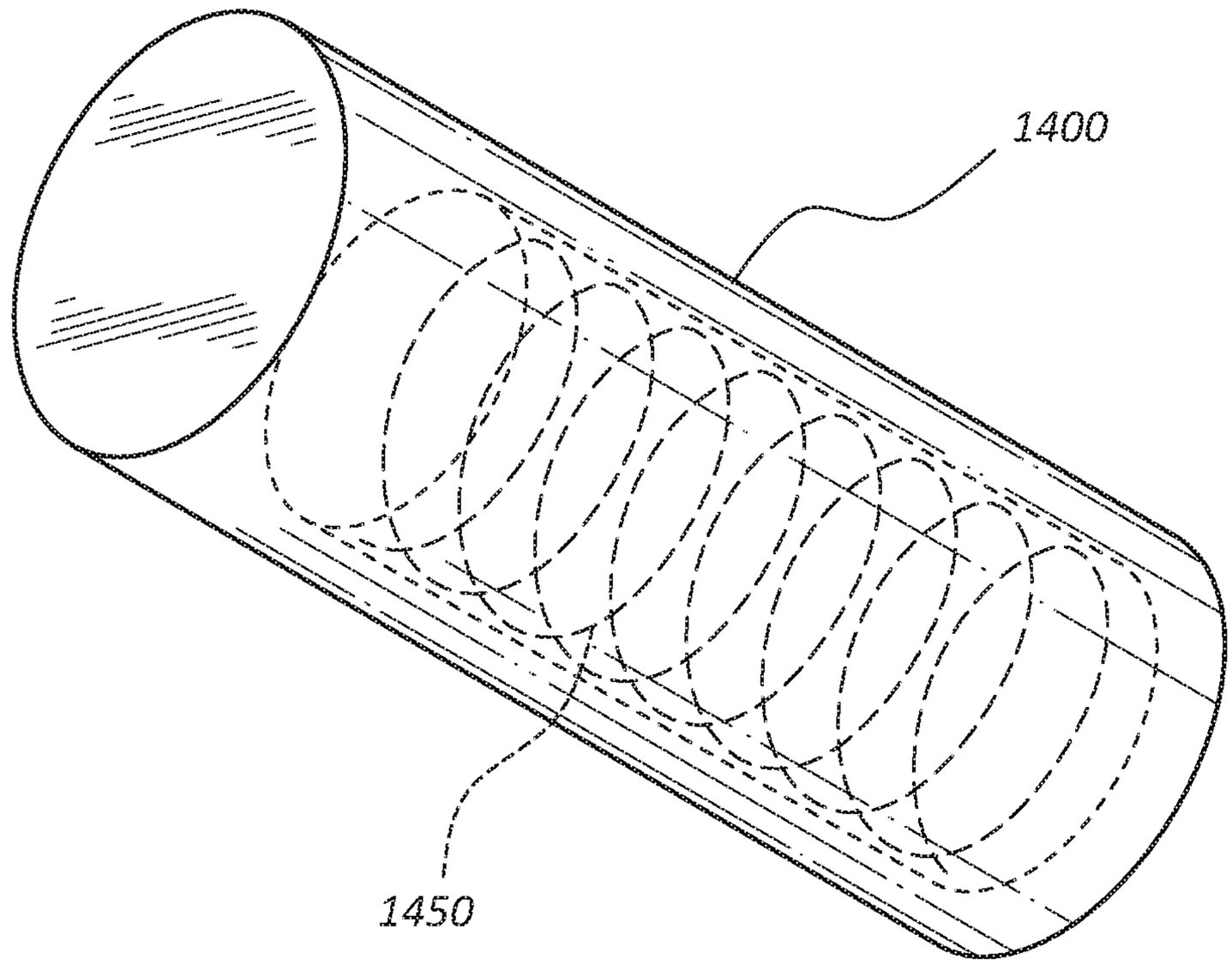

FIG. 21

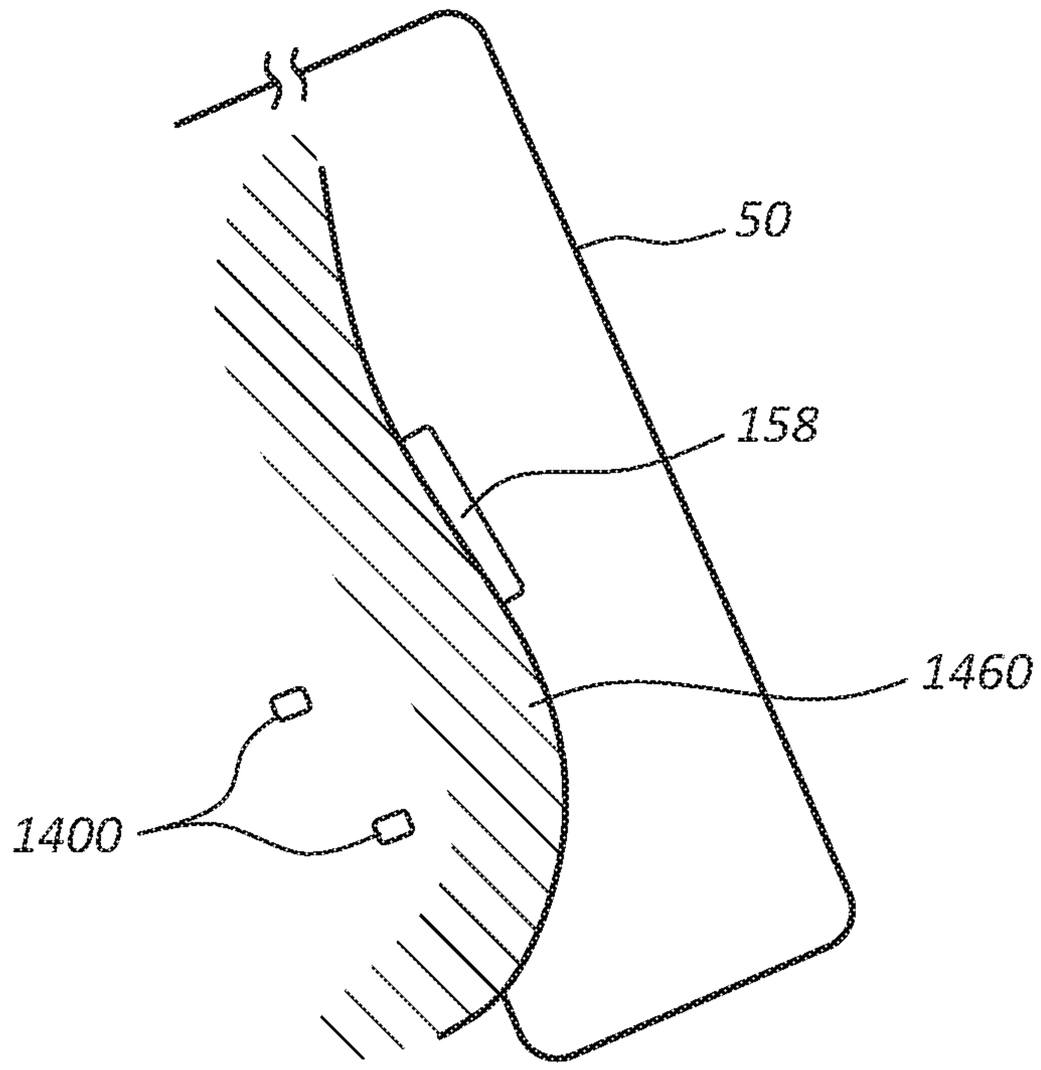

FIG. 22

MULTIPLE COIL SYSTEM FOR TRACKING A MEDICAL DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application No. 62/289,126, filed Jan. 29, 2016, and titled "Multiple Coil System for Tracking an Indwelling Medical Device," which is incorporated herein by reference in its entirety.

BRIEF SUMMARY

Briefly summarized, embodiments of the present invention are directed to a system for tracking the position of one or more medical devices for at least partial insertion into and/or advancement within the body of a patient. The system may also be used to locate one or medical devices at a later time after placement thereof.

The present system includes the use of multiple radiating elements that can be simultaneously detected by a sensor unit of the system, wherein at least one of the radiating elements is included with the medical device, in one embodiment. Another of the radiating elements may be placed at a predetermined point on the skin of the patient to serve as a landmark to help determine the location of the medical device with respect to the landmark.

Detection of the radiating elements by the sensor unit enables the relative positions of the radiating elements to be ascertained and depicted on a display, including two and/or three-dimensional depictions, so as to in turn enable a clinician to observe the relative position of the medical device(s) and landmarks. This assists the clinician in positioning the medical device in a desired position within the patient body.

In one embodiment, therefore, a system for tracking a medical device with respect to a body of a patient is disclosed, comprising a display and a first radiating element. The first radiating element is included with the medical device and is capable of producing a first electromagnetic field. A second radiating element capable of producing a second electromagnetic field is also disclosed and is positioned with respect to the body of the patient. A sensor unit is operably connected to the display, wherein the display is configured for depiction of information relating to detection by the sensor unit of the first and second electromagnetic fields of the first and second radiating elements.

These and other features of embodiments of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of embodiments of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

A more particular description of the present disclosure will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. Example embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

FIG. **1** is a block diagram depicting various elements of an integrated system for intravascular placement of a catheter or other medical device, according to one example embodiment of the present invention;

FIG. **2** is a simplified view of a patient and a catheter being inserted therein with assistance of the integrated system of FIG. **1**;

FIGS. **3**A and **3**B depict various views of the sensor unit of the system of FIG. **1**;

FIG. **4** is a perspective view of an untethered stylet configured in accordance with one embodiment;

FIG. **5** is a cross sectional view of a distal portion of the stylet of FIG. **4**;

FIG. **6** is a simplified block diagram of a control module portion of the untethered stylet of FIG. **4**, together with associated components of the console of FIG. **1**;

FIGS. **7**A and **7**B are various views of a datum module according to one embodiment;

FIG. **8** is a simplified block diagram of a control module portion of the datum module of FIGS. **7**A and **7**B, together with associated components of the console of FIG. **1**;

FIG. **9** is a simplified diagram showing various components employed in synchronizing a pulse signal frequency between a wireless stylet and a console of the system of FIG. **1**;

FIG. **10** is a simplified view of a patient and a catheter being inserted therein with assistance of the integrated system of FIG. **1**;

FIG. **11** is a screenshot as depicted on a display of the integrated system of FIG. **1**, indicating a position of a distal end of the stylet of FIG. **4** during catheter tip placement procedures;

FIG. **12** is a simplified view of a patient and a catheter being inserted therein with assistance of the integrated system of FIG. **1**;

FIG. **13** is a screenshot as depicted on a display of the integrated system of FIG. **1**, indicating a position of a distal end of multiple stylets such as that shown in FIG. **4** during catheter tip placement procedures;

FIG. **14** is a side view of a stylet including multiple radiating elements in accordance with one embodiment;

FIG. **15** is a partial cross sectional view of a vessel including a plurality of stylets positioned therein in accordance with one embodiment;

FIG. **16** is a perspective view of a flexible sensor unit in accordance with one embodiment;

FIG. **17** is a simplified view of the sensor unit of FIG. **16**;

FIGS. **18**A and **18**B depict various views of a needle assembly according to one embodiment;

FIG. **19** is a perspective view of a distal portion of the needle assembly of FIGS. **18**A and **18**B;

FIG. **20** shows the needle assembly of FIGS. **18**A and **18**B in use;

FIG. **21** is a perspective view of a breast marker in accordance with one embodiment; and

FIG. **22** is a partial cross-sectional view showing an imaging operation for breast markers such as those shown in FIG. **21**.

DETAILED DESCRIPTION OF SELECTED EMBODIMENTS

Reference will now be made to figures wherein like structures will be provided with like reference designations. It is understood that the drawings are diagrammatic and schematic representations of exemplary embodiments of the present invention, and are neither limiting nor necessarily drawn to scale.

For clarity it is to be understood that the word "proximal" refers to a direction relatively closer to a clinician using the device to be described herein, while the word "distal" refers to a direction relatively further from the clinician. For example, the end of a catheter placed within the body of a patient is considered a distal end of the catheter, while the catheter end remaining outside the body is a proximal end of the catheter. Also, the words "including," "has," and "having," as used herein, including the claims, shall have the same meaning as the word "comprising."

Embodiments of the present invention are generally directed to a system for tracking the position of one or more medical devices for at least partial insertion into and/or advancement within the body of a patient. The system may also be used to locate one or medical devices at a later time after placement thereof. Examples of medical devices that can be tracked and positioned using the present system include catheters, breast markers, needles, etc.

The present system includes the use of multiple radiating elements that can be simultaneously detected by a sensor unit of the system, wherein at least one of the radiating elements is included with the medical device, in one embodiment. Another of the radiating elements may be placed at a predetermined point on the skin of the patient to serve as a landmark to help determine the location of the medical device with respect to the landmark. Detection of the radiating elements by the sensor unit enables the relative positions of the radiating elements to be ascertained and depicted on a display, including two and/or three-dimensional depictions, so as to in turn enable a clinician to observe the relative position of the medical device(s) and landmarks. This assists the clinician in positioning the medical device in a desired position within the patient body.

In one embodiment, for example, one of the radiating elements includes an electromagnetic coil that is included with a stylet. The stylet is removably received within a lumen of a catheter that is introduced and advanced through the vasculature of the patient. Another radiating element, such as a second electromagnetic coil, is placed atop the chest of the patient to serve as a reference point, or landmark. A sensor unit can be placed in proximity to the patient, such as at the bedside of the patient, so as to enable both electromagnetic coils to be detected during insertion and advancement of the catheter. Detection and tracking of the two electromagnetic coils can enable the clinician to determine if the catheter is being advanced along a desired route or if the catheter has been malpositioned or has encountered an obstacle. In one embodiment, data received from tracking the electromagnetic coils can be used to map the path of catheter advancement, which map can be depicted on a display for use by the clinician, or stored for future reference. Note that more than two coils can be included and used by the system to provide additional data points for accurately detecting the position and advancement of the medical device. Also, more than one medical device can be tracked by the system, in one embodiment.

FIGS. **1** and **2** depict various details of a medical device tracking system ("system" or "tracking system"), generally designated at **10**, which serves as one example environment wherein embodiments of the present disclosure can be practiced. The system **10** is employed to assist a clinician in the placement of a catheter or other medical device(s) within the body of a patient, such as within a vein or other vessel. In one embodiment, the medical device includes a catheter and the intended destination of the catheter within a vein of the patient body is such that the distal tip of the catheter is disposed in the lower $\frac{1}{3}^{rd}$ portion of the superior vena cava ("SVC"). As such, the system assists the clinician by tracking and visualizing advancement of the catheter or other medical device(s) as it advances toward its intended destination within the patient body.

As mentioned, FIGS. **1** and **2** depict various components of the system **10** in accordance with one example embodiment. As shown, the system **10** generally includes a console **20**, display **30**, and sensor unit ("sensor") **50**, each of which is described in further detail below.

FIG. **2** shows the general relation of these components to a patient **70** during a procedure to place a catheter **72** into the patient vasculature through a skin insertion site **73**. FIG. **2** shows that the catheter **72** generally includes a proximal portion **74** that remains exterior to the patient and a distal portion **76** that resides within the patient vasculature after placement is complete. In the present embodiment, the system **10** is employed to ultimately position a distal tip **76**A of the catheter **72** in a desired position within the patient vasculature. In one embodiment, the desired position for the catheter distal tip **76**A is proximate the patient's heart, such as in the lower one-third ($\frac{1}{3}^{rd}$) portion of the Superior Vena Cava ("SVC"). Of course, the system **10** can be employed to place the catheter distal tip in other locations. The catheter proximal portion **74** further includes a bifurcation hub **74**A that provides fluid communication between the one or more lumens of the catheter **72**, one or more extension tubes **74**B extending proximally from the hub, and corresponding connectors **74**C for enabling connection to the catheter **72**.

FIG. **1** shows that a processor **22**, including non-volatile memory such as EEPROM for instance, is included in the console **20** for controlling system function during operation of the system **10**, thus acting as a control processor. A digital controller/analog interface **24** is also included with the console **20** and is in communication with both the processor **22** and other system components to govern interfacing between the sensor **50**, and other system components.

The system **10** further includes ports **52** for connection with the sensor **50** and optional components **54** including a printer, storage media, keyboard, etc. The ports in one embodiment are USB ports, though other port types or a combination of port types can be used for this and the other interfaces connections described herein. A power connection **56** is included with the console **20** to enable operable connection to an external power supply **58**. An internal battery **60** can also be employed, either with or exclusive of an external power supply. Power management circuitry **59** is included with the digital controller/analog interface **24** of the console to regulate power use and distribution.

The display **30** in the present embodiment is integrated into the console **20** and is used to display information to the clinician during the catheter placement procedure. In another embodiment, the display may be separate from the console. In one embodiment, a console button interface **32** can be used to control depiction of images on the display **30** by the clinician to assist in the placement procedure, as will be seen. In one embodiment, the display **30** is an LCD device. Also, the buttons included on the console button interface **32** can be configured in a variety of ways, including the use of user input controls in addition to buttons, such as slide switches, toggle switches, electronic or touch-sensitive pads, etc.

As mentioned, the system **10** is configured to detect and track a plurality of radiating elements associated with one or more medical devices for placement within the body of the patient. Thus, the system **10** enables the clinician to quickly locate and confirm the position and/or orientation of one or more medical devices, such as a peripherally-inserted cen-

tral catheter ("PICC"), central venous catheter ("CVC"), or other suitable catheter or medical device, during initial placement into and advancement through the vasculature or other body portion of the patient **70**.

Briefly, the system **10** is configured to detect electromagnetic radiation, such as an electromagnetic field, generated by a radiating element included with the medical device(s). In the embodiment shown in FIGS. **1** and **2**, for instance, a radiating element (to be described further below) is included proximate the distal tip **76**A of the catheter **72**. The radiating element, together with one or more other radiating elements, is detectable by the sensor unit **50** placed in proximity to the patient, thus enabling the display **30** to graphically depict the detected location of the radiating element, and thus the distal tip **76**A of the catheter **72**. This assists the clinician to ascertain the general location and orientation of the catheter tip within the patient body. It is appreciated that the teachings of one or more of the following U.S. patents may be employed in one embodiment in the above-described tracking: U.S. Pat. Nos. 5,775,322; 5,879,297; 6,129,668; 6,216,028; and 6,263,230. The contents of the afore-mentioned U.S. patents are incorporated herein by reference in their entireties. Note that the system **10** in one embodiment can display the direction in which the catheter distal tip **76**A is pointing, thus further assisting accurate catheter placement. The system **10** in one embodiment can further assist the clinician in determining when a malposition of the catheter tip has occurred, such as in the case where the catheter distal tip **76**A has deviated from a desired venous path into another vein.

In accordance with one embodiment, the above-described radiating element is included with a stylet that is removably inserted into the catheter such that the radiating element is co-terminal with the distal end of the catheter. Further, the stylet including the radiating element is physically untethered to a console or other component of the system **10**. Thus, the stylet itself includes all necessary componentry for producing the electromagnetic field, such as an electrical pulse signal, for use by the system. The stylet in one embodiment further includes functionality to synchronize its pulsing activities with the console **20** of the system **10** such that the system can accurately track advancement of the stylet and its corresponding catheter through the patient vasculature. In another embodiment, the stylet including the radiating element can be tethered to the sensor unit or other component of the system **10** in such a way as to enable the passage of driving signals from the sensor unit **50** or system console **20** to the radiating element through a sterile barrier interposed between the catheter/stylet and sensor unit or console without compromising the barrier itself or the sterile field it helps establish.

As mentioned, the system **10** in the present embodiment utilizes a stylet to enable the distal end of the catheter **72** to be tracked during its advancement through the vasculature. FIGS. **4** and **5** give an example of a detached configuration of such a stylet **130**, configured in accordance with one embodiment. In particular, the stylet **130** in FIGS. **4** and **5** is physically detached, or untethered, from other components of the system **10**. The stylet **130** includes a proximal end **130**A and a distal end **130**B. A control module **102** for the stylet **130**, also referred to herein as a "fob," is included at the stylet proximal end **130**A, with an elongate portion **134** extending distally therefrom.

FIG. **5** gives further details regarding a distal portion of the stylet elongate portion **134** proximate the stylet distal end **130**B. As shown and as mentioned above, the stylet **130** includes a first radiating element **150**, here embodied as an electromagnetic ("EM") coil **106**, which is included proximate the stylet distal end **130**B and is operably connected to leads **106**A. The EM coil **106** and leads **106**A can include insulated copper wire in the present embodiment. The leads **106**A are in turn operably connected to corresponding circuitry located in the stylet control module **132** configured to produce an electric pulse signal so as to enable the EM coil **106** to be electrically pulsed during operation and produce an electromagnetic field having a predetermined frequency or pattern that is detectable by one or more sensors included in the sensor unit **50** during transit of the catheter **72** through the vasculature when the EM coil **106** is within the detectable range of the sensor unit.

Note that the EM coil **106** described herein is but one example of a radiating element, or a component capable of producing electromagnetic radiation, such as an electromagnetic field for detection by the sensor unit. Indeed, other devices and assembly designs can be utilized here to produce the same or similar functionality. For instance, non-limiting examples of other stylet configurations can be found in U.S. Pat. No. 9,901,714, filed Aug. 21, 2009, and entitled "Catheter Assembly Including ECG Sensor and Magnetic Assemblies," which is incorporated herein by reference in its entirety. In the embodiments herein, more than one radiating element is included for use with the system **10**, as will be described further below. In another embodiment, radiating elements of different types (e.g., ultrasonic and electromagnetic) can be included together.

The EM coil **106** and leads **106**A are disposed within tubing **108** that extends at least a portion of the length of the stylet elongate portion **134**. In one embodiment. The tubing includes polyamide. The EM coil **106** and leads **106**A can be protected in other ways as well. A core wire **110** is also included within the tubing **108** in one embodiment to offer stiffness and/or directional torqueability to the stylet elongate portion **134**. The core wire **110** in one embodiment includes nitinol and can extend to the distal end **130**B of the stylet **100** or terminate proximal thereto. In the present embodiment, at least the portion of the core wire **110** that extends within the EM coil **106** includes a ferromagnetic and/or magnetically permeable material, such as iron, iron-containing steel, or other suitable material. Note that the EM coil can be configured in other ways as well; as such, the disclosure herein regarding this and the other radiating elements is not intended to be limiting.

In accordance with the present embodiment, the stylet **130** is untethered, or physically unconnected, with respect to the console **20** of the system **10**. As such, the electric pulsing of the EM coil **106** to produce the predetermined electromagnetic field is driven by suitable componentry included in the fob, or stylet control module **132**, as opposed to pulse driving by the console or other system component to which the stylet would be physically connected. FIG. **6** shows such componentry according to one example embodiment. The control module **132** includes a housing **132**A in which a printed circuit board ("PCB") **232** or other suitable platform is housed. Pulse circuitry **234** is disposed on the PCB **232** and includes a timer circuit **236** configured to provide electrical pulses to the EM coil assembly **106** via the leads **106**A (FIG. **5**). It is noted that in one embodiment the electromagnetic field can be pulsed so as to produce a predetermined pattern, if desired.

A connector **230**A is included on the control module housing **132**A and configured to removably and operably connect with a corresponding connector **230**B included on a proximal end of the stylet elongate portion **134**. In this way, operable connection between the timer circuit **236** and the

EM coil **106** via the leads **106**A is achieved in the present embodiment. Note that other connective schemes between the pulse circuitry **234** and the EM coil **106** can be used. In another embodiment, the stylet elongate portion is permanently connected to the stylet control module.

A power supply **240** is included with the stylet control module **132** to provide power necessary for control module functions, including operation of the pulse circuitry **234** and driving of the electric pulsing performed by the timer circuit **236**. In one embodiment, the stylet **130** is a disposable, one-time use component and as such the power supply **240** is also disposable, such as a button-cell battery. In other embodiments, the power supply can be a rechargeable battery, a long-life power supply, or can be configured to be replaceable as may be appreciated by one skilled in the art. In one embodiment, the stylet control module **132** includes an on/off switch for controlling operation of the control module components.

As mentioned, the timer circuit **236** drives the EM coil **106** by sending electrical pulses at a predetermined frequency to the EM coil via the leads **106**A to which the timer circuit is operably connected. Receipt of the pulses causes the EM coil **106** to emit an electromagnetic field having the predetermined frequency that is detectable by the sensor unit **50** of the system **10**, thus assisting guidance of the catheter **72** (FIG. **2**) as described herein.

In one embodiment, the electric pulse signal of the timer circuit **236** is synchronized with the console **20**, or other system component (such as the sensor unit **50**), to enable the system **10** to identify the frequency of the field produced by the EM coil **106** as a result of the pulsing. This enables the console **20** to identify the proper field relating to the EM coil **106** of the stylet **130** and the sensor unit **50** to accurately track progress of the stylet during intravascular advancement of the catheter **72**. The particular frequency/frequencies employed for the pulse signal in one embodiment comply with applicable laws and regulations, including regulations promulgated by the Federal Communications Commission ("FCC"). In one implementation a frequency of about 1 MHz may be used, for example.

In the present embodiment, synchronization of the pulse signal frequency produced by the timer circuit **236** with the console **20** is achieved by a transmitter **238** included with the stylet control module **132**, as seen in FIGS. **4** and **6**. The transmitter **238** is operably connected to and receives data from the timer circuit **236** relating to the frequency of its pulse signal being sent to the EM coil **106**. The transmitter **238** transmits the data to a receiver **242** included on the console **20**. Receiving the data by the receiver **242**, the console **20** can then identify the electromagnetic field produced by the EM coil **106** when detected by the sensor unit **50** and thus track intravascular advancement of the catheter **72**.

In one implementation, the data transmitted by the transmitter **238** include a message detailing the pulsing frequency of the pulse signal produced by the timer circuit **236**. In another implementation, the data are merely a replication of the pulse signal itself that, when received by the console **20**, enable the console to determine the frequency. The console processor **22** (FIG. **1**) or other suitable console circuitry can be employed to perform this determination functionality. Of course, the data can take any one of a variety of formats and configurations to enable information relating to the pulse signal to be received by the console **20** or other suitable component of the system. In certain embodiments, the console **20**, the sensor unit **50**, or other suitable component of the system **10** can include the necessary circuitry to synchronize with the signal produced by the stylet **130**, as described herein.

The transmitter **238** can transmit, and the receiver **242** receive, the above-referenced data in any number of ways, but in one implementation the transmitter wirelessly transmits via infrared ("IR") or radiofrequency ("RF") radiation wavelengths for receipt by the receiver. As such, for example, the transmitter **238** and receiver **242** can be configured as an IR LED/detector pair in the first case, or as an antenna pair in the second case. Note that other types of transmitter/receiver configurations can be included to perform the intended functionality described herein. Other forms of electromagnetic radiation can be employed to transmit data, including visible light in one embodiment. Also note that the transmitter **238** and the receiver **242** can each serve as transmitters/receivers in this and other embodiments herein.

In one embodiment, the timer circuit of the untethered stylet control module is configured to be adjustable such that the pulse frequency can be selected from a plurality of predetermined frequency options. Such functionality may assist in the case where interference exists on one or more of the predetermined frequencies, where different stylets are used successively by the same system (as discussed below), or where multiple systems are used simultaneously in close proximity to one another. In such a configuration, a selector switch may be included on the control module housing **132**A, the console **20**, and/or other suitable system component. The above or other suitable synchronization scheme can be used to coordinate the selected pulse frequency to be transmitted and received between the stylet control module and the console.

In another implementation, the stylet control module/console automatically switches to one of a plurality of possible pulse frequencies for use in driving the EM coil. In this latter implementation, the console can be configured to successively scan the plurality of possible frequencies and perform frequency identification functions, including phase locking (e.g., via a phase locking circuit), to identify the frequency on which the stylet control module timer circuit is producing the electrical pulse signal, as well as the frequencies of other EM coils of the system, thus enabling synchronization of the console therewith.

FIG. **9** shows an example of the above automatic synchronization implementation, according to one embodiment. As shown, a transmitter such as an antenna **239** is included with the stylet control module **132** and is configured to emit radiofrequency ("RF") or other suitable signals. A receiver such as an antenna **243** is included with the console **20** of the system **10** to receive signals emitted by the stylet control module antenna **239**. The console **20** further includes various components for processing signals received by the antenna **243**, including a mixer **363**, an oscillator **365**, a low pass filter **364**, an analog-to-digital converter ("ADC") **367**, and a digital signal processor ("DSP") **368**.

During operation of the system **10**, the stylet antenna **239** of the stylet control module **132** emits an RF or other suitable signal (e.g., infrared ("IR")) that provides data relating to the frequency of the pulse signal. The RF signal is received by the console antenna **242**. The mixer **363** combines the signal received by the antenna **242** with a predetermined signal generated by the oscillator **365**, which combined signal is then filtered through the low pass filter **364** to remove any extraneous signals. The filtered and combined signal is passed through the ADC **367**, then analyzed by the DSP **368** to determine whether the two

signals forming the combined signal match. If so, phase shifting of the signals will be performed by the DSP and/or oscillator **365** to lock the signals in phase.

If the signals do not match, the above process is repeated with a new signal having a different frequency being produced by the oscillator **365**. The above process is iteratively repeated until the signal from the oscillator **365** matches in frequency the signal emitted by the stylet control module antenna **239** and subsequently received by the console antenna **242**. Thus, the oscillator **365** in one embodiment is capable of cycling through a plurality of pre-set signal frequencies in attempting to match the emitted signal of the stylet control module antenna **239**. In another embodiment, the oscillator can cycle through a range of frequencies in attempting to match the emitted signal. As noted before, once the proper signal frequency is determined by the console **20**, phase shifting as needed can be conducted to complete synchronization between the EM coil **106** of the stylet **130** and the console **20**, thus enabling the console to track the EM coil.

It is understood that the above is merely one example of synchronizing the pulse signal produced by the stylet coil assembly with the console and that other implementations can be employed to link the frequency between the stylet coil assembly and console or other component of the system.

In another embodiment, it is appreciated that the transmitter/receiver configuration can be reversed such that the transmitter is included with the console and directs information regarding the frequency of the pulse signal to the stylet control module, which receives the information via a receiver included therein. In yet another embodiment, both the stylet and the console are manufactured to operate with a pre-set pulse signal frequency, requiring no subsequent synchronization therebetween. These and other possible configurations are therefore contemplated. Generally, it should be understood that the pulse circuitry and timer circuit of the stylet control module, together with the processor of the console **20**, can be configured in one or more of a variety of ways to achieve above-described functionality. For instance, the processor **22** of the console **20** can be included in the sensor unit **50** (FIGS. **1**, **3**) such that synchronization operations on behalf of the system **10** are performed by the sensor unit. Or, in another embodiment the stylet functionality is incorporated into the catheter itself and no removable stylet is employed.

As mentioned, the system **10** in the present embodiment utilizes multiple radiating elements to assist in tracking a medical device(s) as it is inserted into a patient body and/or to locate the medical device post-insertion. As discussed above the radiating element **150**, implemented as the EM coil **106** included in the catheter stylet **130**, serves as the first radiating element to provide an electromagnetic field that can be tracked by the system **10**. FIGS. **7**A and **7**B show a datum module **158** that houses a second radiating element **160**, implemented in the present embodiment as an electromagnetic ("EM") coil **276** configured to an electromagnetic field detectable by the sensor unit **50** of the system **10**, similar to the detection of the EM coil **106** of the stylet **130**, and depicted graphically on the display **30** of the system **10**. In the present embodiment, the datum module **158** is employed to serve as a reference point or external landmark (e.g., external marker) to assist in determining the location of the EM coil **106** of the stylet **130** as the catheter **72** is advanced through the vasculature of the patient. As such, in the present embodiment the datum module **158** can be placed on a skin surface of the patient **70** and, when detected by the sensor unit **50** can help determine the location of the EM coil **106** of the catheter stylet by depicting on the display **30** a positional relationship between the EM coil **106** and the EM coil **276** of the datum module **158**, which itself is located at a landmark on the patient skin surface.

FIGS. **7**A and **7**B depict various details of the datum module **158**, in accordance with the present embodiment. As shown, the datum module **158** includes an outer housing **250** that houses various components such as those shown in simplified form in FIG. **7**B, including a PCB **262** and a power source **270**, such as a battery. Also shown in the housing **250** is the second radiating element **160** referred to above, here implemented as the EM coil **276**, though it is appreciated that type of other radiating elements can also be employed here, as is the case with the other radiating elements referred to herein. The EM coil **276** is operably connected to the power source **270** via insulted copper wire leads or the like to enable the EM coil to emit electric pulse signals during system operation. As is the case with the stylet **130** and its EM coil **106**, the datum module **158** and its EM coil **276** are physically detached, or untethered, from other components of the system **10**. The datum module housing **250** includes various other components for controlling operation of the datum module **158** and its interaction with the system **10** in tracking medical devices.

The datum module **158** is configured to produce an electric pulse signal via its EM coil **276** such that the resultant electromagnetic field having a predetermined frequency or pattern is detectable by the sensors included in the sensor unit **50**. As mentioned, detection of the datum module **158** by the sensor unit **50** enables it to serve as a reference point/landmark during transit of the catheter **72** and its corresponding EM coil-equipped stylet **130** through the vasculature.

FIG. **8** depicts the various components included in the datum module **158** to enable it to operate as an untethered component as described herein in accordance with the present embodiment, namely, the electric pulsing of the EM coil **276** to produce the predetermined electromagnetic field. The components include a printed circuit board ("PCB") **262** or other suitable platform, pulse circuitry **264** disposed on the PCB, and a timer circuit **266** configured to provide electrical pulses to the EM coil **276**. It is noted that in one embodiment the electromagnetic field can be pulsed so as to produce a predetermined pattern, if desired.

A power supply **270** is included with the stylet control module **132** to provide power necessary for control module functions, including operation of the pulse circuitry **264** and driving of the electric pulsing performed by the timer circuit **266**. In one embodiment, the datum module **158** is a disposable, one-time use component and as such the power supply **270** is also disposable, such as a button-cell battery. In other embodiments, the power supply can be a rechargeable battery, a long-life power supply, or can be configured to be replaceable as may be appreciated by one skilled in the art. In one embodiment, the datum module **158** includes an on/off switch for controlling its operation.

As with the EM coil **106** of the stylet **130**, the timer circuit **266** of the datum module **158** drives the EM coil **276** by sending electrical pulses at a predetermined frequency to the EM coil to which the timer circuit is operably connected. Receipt of the pulses causes the EM coil **276** to emit an electromagnetic field having the predetermined frequency that is detectable by the sensor unit **50** of the system **10**, as described herein.

In one embodiment, the electric pulse signal of the timer circuit **266** is synchronized with the console **20**, or other system component (such as the sensor unit **50**), to enable the

system **10** to identify the frequency of the field produced by the datum module EM coil **276** as a result of the pulsing. This enables the console **20** to identify the proper field relating to the EM coil **276** of the datum module **158** and to differentiate it from the electromagnetic fields of other radiating elements of the system **10**, such as the EM coil **106** of the stylet **130**, discussed above. This in turn enables the sensor unit **50** and system **10** to accurately track progress of the stylet **130** during intravascular advancement of the catheter **72** as well as track the position of the datum module **158** as a reference point to assist in localizing the position of the stylet (or other medical device) with respect to the datum module. As before, the particular frequency/frequencies employed for the pulse signal in one embodiment comply with applicable laws and regulations, including regulations promulgated by the Federal Communications Commission ("FCC").

In the present embodiment, synchronization of the pulse signal frequency produced by the timer circuit **266** with the console **20** is achieved by a transmitter **268** included with the datum module **158**, as seen in FIG. **8**. The transmitter **268** is operably connected to and receives data from the timer circuit **266** relating to the frequency of its pulse signal being sent to the EM coil **276**. The transmitter **268** transmits the data to the receiver **242** included on the console **20**. Receiving the data by the receiver **242**, the console **20** can then identify the electromagnetic field produced by the datum module EM coil **276** when detected by the sensor unit **50**, differentiate it from the signals of any other EM coils of the system **10**, and thus track both the intravascular advancement of the catheter **72** and the position of the datum module **158**. The configuration and operation of the transmitter **268** and the receiver **242** is similar to that described in connection with the transmitter **238** and receiver **242** with respect to the stylet control module **132**, further above. Indeed, operation of the components of the datum module **158** shown in FIG. **8** is similar to that described in connection with the components of the stylet control module **132** of FIG. **6**. Further, the discussion relating to an automatic synchronization of pulse signal frequency between the stylet control module **132** and the console **20** detailed above in connection with FIG. **9** also corresponds to synchronization of the datum module **158** with the console, in the present embodiment, with the antenna **239** representative of an antenna included with the datum module **158**. In another embodiment, it is appreciated that the pulse signals of the EM coils of the system can be multiplexed together (such as via time-based multiplexing), instead of differing in frequency/wavelength. As such, this and other modes for distinguishing the pulse signals of the various radiating elements are appreciated.

As seen in FIGS. **3**A and **3**B and as mentioned above, the system **10** includes a sensor unit **50** for detecting the position and movement of the first and second radiating element, i.e., the EM coil **106** of the stylet **130** and the EM coil **276** of datum module **158** in the present embodiment, during a procedure to place or locate a medical device within the body of a patient. The sensor unit **50** includes a sensor array **190** comprising a plurality of sensors **192** embedded within the housing of the sensor unit. The sensors **192** are configured to detect a magnetic field (a segment of its electromagnetic field) produced by the EM coils **106**, **276**, as well as any other radiating elements that are part of the system **10**, such as in the case of multiple EM coils used to track a plurality of medical devices. Though they are shown in FIGS. **3**A and **3**B as included with the sensor unit **50** having a certain size and shape, the sensors **192** of the sensor array **190** can be included in a sensor unit having a different shape, size, or other configuration. In the present embodiment, the sensors **192** are disposed in a planar configuration below a top face of the sensor unit **50**, though it is appreciated that the sensors can be arranged in other configurations, such as in an arched or semi-circular arrangement.

In the present embodiment, each of the sensors **192** includes three orthogonal sensor coils for enabling detection of a magnetic field in three spatial dimensions. Such three dimensional ("3-D") magnetic sensors can be purchased, for example, from Honeywell Sensing and Control of Morristown, N.J. Further, the sensors **192** of the present embodiment are configured as Hall-effect sensors, though other types of magnetic sensors could be employed. Further, instead of 3-D sensors, a plurality of one dimensional magnetic sensors can be included and arranged as desired to achieve 1-, 2-, or 3-D detection capability.

In the present embodiment, six sensors **1192** are shown included in the sensor array **190** so as to enable detection of the EM coils **106**, **276** in not only the three spatial dimensions (i.e., X, Y, Z coordinate space), but also the pitch and yaw orientation of the EM coil itself. Note that in one embodiment, orthogonal sensing components of two or more of the sensors **192** enable the pitch and yaw attitude of the EM coil **106** for instance, and thus the medical device, to be determined.

In other embodiments, fewer or more sensors can be employed in the sensor array. More generally, it is appreciated that the number, size, type, and placement of the sensors of the sensor array can vary from what is explicitly shown here. In one embodiment, at least three sensors are employed.

The placement of the sensor unit **50** can be varied according to type of medical device placement scenario, the logistics of the insertion procedure, etc. For instance, FIG. **2** shows the sensor unit **50** positioned at a side of the patient **70** where it can detect the electromagnetic fields produced by the EM coils **106**, **276**. Such a placement may be used to position the sensor unit **50** at the bedside of the patient **70** in a hospital or clinic setting, for instance. However, multiple other placements of the sensor unit **50** are possible, including on the chest or other skin surface of the patient, adjacent a body part of interest, etc. Note further that the size, shape, and other configuration of the sensor unit can vary from what is explicitly shown and described herein.

Reference is made to FIGS. **2** and **10**, which depict disposal of the untethered stylet **130** substantially within a lumen in the catheter **72** such that the proximal portion thereof, including the control module **132**, extends proximally beyond the catheter lumen, the hub **74**A and a selected one of the extension legs **74**B. So disposed within a lumen of the catheter, the first radiating element **150**, implemented as the EM coil **106** and located proximate the distal end **130**B of the stylet **130**, is substantially co-terminal with the distal catheter end **76**A such that detection by the system **10** of the stylet EM coil correspondingly indicates the location of the catheter distal end. Further, the datum module **158**, including the second radiating element **160** implemented as the EM coil **276**, is also shown sitting atop a central portion of the chest of the patient **70**, though it is appreciated that this is just one of a variety of possible placement locations for the datum module, both on or off the patient body, to serve as a reference marker. It is appreciated that both EM coils **106**, **276** are powered and operating during the procedure so as to produce their respective electromagnetic fields for detection.

Note that the electromagnetic field of each EM coil includes a unique characteristic unique within the system **10** so as to be distinguishable and separately trackable by the system. This is accomplished in one embodiment by each EM coil producing an electromagnetic field that differs in frequency and/or amplitude from the other EM coil(s) of the system. Such differentiation of electromagnetic fields can be configured as a permanent configuration for each EM coil at the time of manufacture/setup of the system **10**, in one embodiment. In another embodiment, the system can actively assign and/or change the EM coil configurations using the teachings discussed above in connection with FIG. **9**. Of course and more generally, other modes of producing unique types of electromagnetic radiation from each radiating element are also contemplated herein. In one embodiment, the electromagnetic fields of the EM coils are time multiplexed together or treated to other multiplexing operations. Thus, this is another example of a unique characteristic the radiating elements can possess in order to be differentiated by the system.

The sensor unit **50** is employed by the system **10** during operation to detect the electromagnetic field produced by the EM coil **106** of the stylet **130**. As mentioned above, the sensor unit **50** is placed in the present embodiment to the side of the patient **70** during catheter insertion, one of a plurality of possible locations for the sensor unit to reside, to enable the field of the EM coil **106**, disposed in the catheter **72** as described above, to be detected during catheter transit through the patient vasculature. Again, as the EM coil **106** is substantially co-terminal with the distal end **76**A of the catheter **72** (FIG. **2**), detection by the sensor unit **50** of the field produced by the EM coil **106** provides information to the clinician as to the position and orientation of the catheter distal end **76**A during its transit.

FIGS. **2** and **10** further depict the datum module **158** positioned on a central chest portion of the patient **70**. So disposed, the second radiating element **160**, implemented here as the EM coil **276**, is prepared for detection by the sensor unit **50** and to serve as a reference marker.

In greater detail, the sensor unit **50** is operably connected to the console **20** of the system **10** via the console cable **140** and one or more of the ports **52**, as shown in FIGS. **1** and **2**. Note that other connection schemes between the sensor unit **50** and the system console **20** can also be used without limitation. As just described, the EM coil **106** is employed in the stylet **130** to enable the position of the catheter distal end **76**A (FIG. **2**) to be observable relative to the sensor unit **50** placed to the side of the patient. Detection by the sensor unit **50** of the stylet EM coil **106** is graphically displayed on the display **30** of the console **20** during system operation, represented in FIG. **11** (discussed below), for example. In this way, a clinician placing the catheter **72** is able to generally determine the location of the catheter distal end **76**A within the patient vasculature relative to the sensor unit **50** and detect when catheter malposition, such as advancement of the catheter along an undesired vein, is occurring.

Correspondingly, the EM coil **276** of the datum module **158** is employed to serve as a reference point for assisting location of the EM coil **106** associated with the catheter (or other medical device). Detection by the sensor unit **50** of the datum module EM coil **276** can be graphically displayed on the display **30** of the console **20** during system operation. This is shown in FIG. **11**, which depicts a screenshot **380** of the display **30** during operation of the system **10**. As shown, the screenshot **380** depicts a simplified stock outline body image **382**. Also shown is an icon **390** that represents the EM coil **106** disposed at the distal end of the stylet **130** and disposed in one of the lumens of the catheter **72** as it is being inserted through a vein of the patient **70** (FIG. **2**). The icon **390** shows the position of the EM coil **106** as detected by the sensor unit **50** of the system **10**. Also shown in broken line trailing the icon **390** is the previous path of the EM coil **106** as it traversed through the vein.

FIG. **11** further shows an icon **394** that represents the EM coil **276** of the datum module **158** that is positioned atop a central chest portion of the patient **70**, as shown in FIG. **2**. The icon **394** shows the position of the EM coil **106** as detected by the sensor unit **50**. As the datum module **158** is kept relatively stationary during the catheter insertion procedure, the icon **394** stays relatively in place as depicted on the screenshot **380** of the display **30**. FIG. **10** shows that the system **10**, by virtue of the ability of the sensors **192** of the sensor unit **50** to detect the relative positions of both EM coils **106** and **276**, can determine (among other positional relationships) a distance z between the EM coil **106** and the EM coil **276** in real-time, thus determining a distance in the z-direction existing between the distal **76**A of the catheter **72** disposed within the vein and the skin surface of the central chest of the patient **70** where the datum module **158** is disposed. In this way, the datum module **158**, with its EM coil **276**, serves as a reference marker to further assist in determining the location of the catheter **72** (or other medical device) with respect to a landmark, such as the chest of the patient **70**.

Note that the icon **390** shown in FIG. **11** includes a central dot surrounded by a varying number of concentric circles, wherein more circles indicate a relatively deeper depth of the EM coil **106** as detected by the sensor unit **50**. The icon **394** representing the datum module **158** includes a dot surrounded by a diamond. Of course, it is appreciated that a variety of other shapes and configurations can be employed for the icons **390**, **394**. Note further that various depiction modes can be depicted by the display in one embodiment, include two-dimensional and three-dimensional representations. Also, it is appreciated that the tracking of one or more radiating elements as described herein can enable a clinician in one embodiment to map a portion of a vasculature or other structure of the patient, as well as identify medical device mal-positions, obstacles/obstructions to advancing the medical device, arterial vs. venous catheter placements, IVC vs. SVC device placement, innominate vein/artery placement, etc. The system may be used in one embodiment for delicate medical device placement, including neo-natal placements, placements where the patient is wearing a neck brace or other obstruction that would otherwise make medical device placement difficult, etc.

It should be appreciated that in one embodiment the positions of the radiating element and the sensor can be reversed such that a remotely powered sensor is included with the stylet and with the datum module for detecting a field produced by a radiating element positioned external to the body of the patient.

FIG. **12** depicts a system configuration according to another embodiment wherein the catheter **72**, including the EM coil-equipped stylet **130**, is inserted into a femoral vein at an insertion site **73** on an upper leg of the patient **70**. The datum module **158** including its EM coil **276** is positioned on a lower torso portion of the patient **70**. The sensor unit **50** is positioned to the side of the patient **70**. The embodiment of FIG. **12** depicts one of many possible implementations for the system **10**, including insertion of a catheter through a lower portion of the patient body, for instance. As such, it should be appreciated that a variety of different catheters can

be placed by the system **10** as described herein, including urinary, ablation, arterial, PICC, CVC, etc.

FIG. **13** depicts a system configuration according to another embodiment, showing the screenshot **380** with the stock body image **382** superimposed thereon. Two icons **390** are shown, representing EM coils included on stylets that are disposed in two separate catheters that are being inserted into different locations within the body of the patient. In addition, two icons **394** are shown, representing two EM soil-equipped datum modules **158** that are disposed at different locations on the chest of the patient, such as bordering the perimeter of the heart, for instance. Thus, this embodiment demonstrates the ability of the system **10** to track more than two radiating elements, such as EM coils, in order to assist in the placement of two or more medical devices simultaneously. It should be appreciated that a variety of different combinations of radiating elements associated with datum modules and medical devices may be employed by the system **10**. For instance, in one embodiment, four EM coils or other type of suitable radiating elements can each be included with three datum modules and one medical device, for instance, in order to track the medical device to an intended destination within the patient body. These and other configurations are therefore contemplated.

Note that, in one embodiment, the control module housing **132**A of the stylet **130** can serve as a handle to assist in manipulating the catheter **72** and/or stylet during intravascular advancement. Note also that the untethered nature of the stylet **130** and the datum module **158** enable their use in a sterile setting without need to pierce a sterile barrier established around the patient during the medical device insertion procedure with wires or other connection modes. However, in another embodiment, it is appreciated that the EM coils can be operated via wire attachment if desired.

It should appreciated herein that "stylet" as used herein can include any one of a variety of devices configured for removable placement within a lumen of the catheter to assist in placing a distal end of the catheter in a desired location within the patient's vasculature. In one embodiment, the stylet includes a guidewire. As such, it is appreciated that stylets of other forms and configurations can also be acceptably used, in accordance with the present disclosure.

FIG. **14** depicts a system configuration according to another embodiment, wherein the stylet **130** includes dual radiating elements, i.e., a first radiating element **150** disposed proximate the distal end of the stylet and an additional radiating element **162** disposed proximal to the first radiating element. Thus, it is appreciated that the distribution as well as the number of radiating elements can vary.

FIG. **15** depicts a system configuration according to another embodiment, wherein first and second stylets **130**, **131** are disposed within a vessel **406**, such as a vein. In one embodiment, the first stylet **130** is guided by a clinician to one of multiple stenoses **404** present in the vessel **406**, at which point further advancement is ceased. The second stylet **131** can then be introduced into the vessel **406** and guided by the system **10** to another of the stenoses **404**, where further advancement is then ceased. The location of the stenoses can be confirmed and noted using the location ability of the system **10**, wherein remedial procedures can be undertaken to remove the stenoses **404**.

FIGS. **16** and **17** depict details of the sensor unit **50** according to another embodiment, including a flexible body, or flexible sheet **410**, wherein a plurality of sensors **192** is disposed in a spaced-apart arrangement. Such a flexible sensor unit **50** can enable sensor placement on areas of the patient body, for instance, where curvature or body features would otherwise make sensor unit placement difficult.

FIG. **17** shows that, in the present embodiment, each sensor **192** disposed within the flexible sheet **410** has positioned adjacent to it an EM coil **414**. So configured, the sensor unit **50** can be shaped as desired before operation of the system **10** is commenced. For instance, the flexible sheet **410** can be bent around a thigh of the patient. Then, the EM coils **414** of each sensor **192** can be activated so that the system **10** can determine the positional relationship of the sensors via a calibration operation. Thereafter, the sensor unit **50** is ready to be used in detecting EM coils, such as the EM coils **106**, **276** described further above. Should the flexible sensor unit **50** be moved or readjusted in placement, another calibration of the sensors **192** would be performed before resuming system operations.

FIGS. **18**A, **18**B, and **19** depict details regarding another example of a medical device that can be used with the system **10**, in accordance with one embodiment. As shown, a needle assembly **1200** is shown, including a hub **1304** from which extends a hollow cannula **1202**. A needle safety component **1320** is included is disposed on a distal end of the hub **1304**. A control module **1314** is shown attached to a proximal end of the hub **1304**. A hole **1312** is shown defined through the control module **1314** and hub **1304**.

A stylet **1390** extends from the control module **1314** and distally through the hub **1304** via the hole **1312** to extend into the lumen defined by the cannula **1202**. A radiating element **1350**, such as an EM coil **1392**, is disposed proximate a distal end of the stylet **1390**. The control module **1314** can include threads so as to threadably engage the needle hub **1304** or other suitable component of the needle or medical component. In this way, the stylet **1390** and associated EM coil **1392** is removably attachable to the needle **1200**. Thus, the radiating element **1350** need not be permanently affixed or included with the needle **1200**, but rather can be removed therefrom when EM coil-based needle guidance is no longer needed. In addition, this enables the stylet **1390** and control module **1314** to be attached to many different types and sizes of needles. Note that in the present embodiment the distally slidable needle safety component **1320** is configured to safely isolate the distal tip of the needle **1200** upon removal of the needle from the patient.

The EM coil **1392** of the stylet **1390** as shown here enables the distal tip of the needle **1200** to be tracked and located when it is inserted into a patient in a manner similar to what has been described in previous embodiments, and as depicted in FIG. **20**. As shown in FIG. **20**, the distal portion of the needle cannula **1202** is shown inserted into the body of the patient. The stylet **1390** is inserted into the cannula **1202** such that the EM coil **1392** is disposed proximate the distal end of the cannula. Additionally, the datum module **158**, including its own EM coil **276** (FIGS. **7**B, **8**), is disposed on a skin surface above the subcutaneous needle cannula **1202**. In this configuration, the system **10** is able to track and depict on the display **30** the locations of the EM coils **276**, **1392** of the datum module **158** and the needle stylet **1390**, respectively, using the detection thereof by the sensor unit **50**. This in turn enables the clinician to accurately guide the distal end of the needle cannula **1202** to a desired location within the patient body. Thus, the present embodiment of FIGS. **18**A-**19** serves as one of many examples of medical devices that can be tacked and guided by the present system **10**.

FIGS. **21** and **22** depict details regarding another example of a medical device that can be used with the system **10**, in

accordance with one embodiment. As shown, a marker device, such as a breast marker **1400**, includes in the present embodiment a radiating element **1450**. The radiating element **1450** in the present embodiment is a reactive or resonating type of EM coil, which resonates electromagnetically when induced by an external field provided by a suitable power source. As shown in FIG. **22**, in one example implementation multiple breast markers **1400** are disposed in breast tissue **1460** of a patient, wherein each breast markers includes a resonating-type radiating element **1450**. The datum module **158**, including its EM coil **276**, is placed on a skin surface of the breast. The sensor unit **50** can be placed in proximity to the breast to enable the location of the breast markers **1400** and the datum module **158** to be detected and located by the system **10**, thus enabling the clinician to determine the location of the breast markers at some point in time after initial implantation of the breast markers. Note that in one embodiment the sensor unit **50** includes a suitable power source to produce the responsive electromagnetic fields in the resonating-type radiating elements **1450** of the breast markers **1400**. Thus, this serves as yet another example of a medical device that can benefit from the tracking and location ability of the system **10**.

Note that further details regarding untethered stylets and tracking systems can be found in U.S. Pat. No. 9,526,440, filed Jun. 19, 2014, and entitled "System for Placement of a Catheter Including a Signal-Generating Stylet," which is incorporated herein by reference in its entirety. Note further that other guidance modalities can be included with the system **10**, including permanent magnet-based tracking, ultrasound imaging, and ECG-related guidance.

Embodiments of the invention may be embodied in other specific forms without departing from the spirit of the present disclosure. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the embodiments is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A system for tracking a catheter in a body of a patient, comprising:

a display;

a stylet designed for insertion through a lumen of the catheter, the stylet comprising:

a stylet control module at a proximal end of the stylet, the stylet control module including a first power source and a first timer circuit, the first timer circuit designed to send an electrical pulse signal at a first predetermined frequency to a distal end of the stylet; and

a first radiating element at the distal end of the stylet, the first radiating element designed to emit a first electromagnetic field with the first predetermined frequency;

a datum module, comprising:

a housing;

a second power source and a second timer circuit enclosed by the housing, the second timer circuit designed to send an electrical pulse signal at a second predetermined frequency; and

a second radiating element connected to the second timer circuit in the housing, the second radiating element designed to emit a second electromagnetic field with the second predetermined frequency; and

a sensor unit operably connected to the display, the sensor unit designed to detect the first electromagnetic field in at least three spatial dimensions and to detect a position of the second radiating element with respect to the first radiating element, the display configured for depiction of information relating to detection by the sensor unit of the first electromagnetic field and the second electromagnetic field.

2. The system as defined in claim **1**, wherein the sensor unit includes an array of six sensors.

3. The system as defined in claim **2**, wherein the display is included in a console and wherein the sensor unit is operably connected to the console.

4. The system as defined in claim **1**, wherein the sensor unit is movable and is configured for placement on a portion of the body of the patient.

5. The system as defined in claim **1**, wherein the stylet control module and the datum module wirelessly communicate with the sensor unit.

6. The system as defined in claim **3**, wherein the first predetermined frequency is different from the second predetermined frequency.

7. The system as defined in claim **6**, wherein the first electromagnetic field and the second electromagnetic field are time multiplexed together.

8. The system as defined in claim **6**, wherein the first predetermined frequency and the second predetermined frequency can be changed via communication between the console, the stylet control module, and the datum module.

9. The system as defined in claim **8**, wherein the stylet control module and the datum module communicate with the console via either infrared or radiofrequency radiation wavelengths.

10. The system as defined in claim **9**, wherein each of the stylet control module and the datum module includes a transmitter to transmit data relating to the first timer circuit and the second timer circuit, respectively, to the console.

11. The system as defined in claim **1**, wherein the stylet control module is configured as a handle to assist in manipulating the catheter.

12. The system as defined in claim **1**, wherein the first radiating element includes a first electromagnetic coil, and wherein the second radiating element includes a second electromagnetic coil.

13. The system as defined in claim **12**, wherein the stylet includes an additional electromagnetic coil positioned at the distal end of the stylet proximal to the first electromagnetic coil.

14. The system as defined in claim **1**, wherein the datum module is designed to be placed proximate an external landmark of the body of the patient body.

15. The system as defined in claim **14**, wherein a detected position of each of the first radiating element and the second radiating element is depicted on the display, and wherein the display further depicts a representation of a portion of the body of the patient.

16. The system as defined in claim **15**, wherein the detected position of each of the first radiating element and the second radiating element is depicted on the display by a first icon and a second icon, respectively.

17. The system as defined in claim **1**, wherein the sensor unit is in the form of a flexible sheet, wherein a plurality of sensors is disposed in a spaced apart arrangement within the flexible sheet.

18. The system as defined in claim **17**, wherein an electromagnetic coil is positioned adjacent each of the plurality of sensors in the flexible sheet.

19. The system as defined in claim **1**, further comprising a third radiating element positioned at a distal end of a second stylet, the second stylet comprising a second stylet control module connected to the third radiating element.

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